United States Court of Appeals

for the Second Circuit

SUPPLEMENTAL APPENDIX

74-2284

Nos. 74-2345, 74-2285, 74-2286
74-2308, 74-2440, & 74-2441

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

THE B.F. GOODRICH COMPANY,

Petitioner,

v.

PETER J. BRENNAN, ET AL.,

Respondents.

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.,

Petitioner,

v.

OCCUPATIONAL SAFETY AND HEALTH
ADMINISTRATION, ET AL.,

Respondents.

HOOKER CHEMICALS & PLASTICS CORPORATION,

Petitioner,

v.

OCCUPATIONAL SAFETY AND HEALTH
ADMINISTRATION, ET AL.,

Respondents.

UNION CARBIDE CORPORATION,

Petitioner,

v.

UNITED STATES DEPARTMENT OF LABOR, ET AL.,

Respondents.

VOLUME I

AIR PRODUCTS AND CHEMICALS, INC.,

Petitioner,

v.

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION, ET AL.,

Respondents.

TENNECO CHEMICAL, INC.,

Petitioner,

v.

OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION, ET AL.,

Respondents.

SUPPLEMENTAL APPENDIX

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VOL. I

Rubber, and Goodyear reported that some employees who were

[illegible]

month."

Signed [illegible].

Based upon the [illegible] and the Industrial Bio-Test [illegible] in persons exposed to vinyl chloride, our present judgment is that vinyl chloride is a [illegible] agent.

[illegible] material [illegible]. For example, the [illegible] However, the [illegible] with us today, and it is [illegible] rapidly [illegible]

[illegible]

[illegible] considerations in draft- [illegible]

[illegible] polyvinyl chloride, [illegible] Thus, the [illegible] which, in turn, is [illegible]

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[illegible]

DR. [illegible]: Your Honor, Judge [illegible], Mr. Boyd.

I am Dr. [illegible] P. [illegible], Scientific Consultant [illegible] Cancer Institute.

I have a Ph.D. degree in Biochemistry and have broad [illegible] a master's degree in [illegible]

[illegible]

[illegible] and not go into great [illegible] taking place on the [illegible] that will [illegible] appeared in various [illegible] Professor [illegible]; the [illegible] Industrial Bio-Test Laboratories, who I [illegible] in this hearing.

Rather, I would dwell on certain concepts and principles concerning the carcinogenicity of vinyl chloride. The rare and [illegible] fatal form of cancer, angiosarcoma of the liver, [illegible] vinyl chloride and the polyvinyl chloride [illegible] in occupational exposure to this chemical, which has previously been shown to induce angiosarcoma [illegible] animals.

[illegible] reports on [illegible] induced [illegible] in the wide usage of the chemical, and its [illegible] economic importance. Only two other chemicals have previously been reported to induce this rare neoplastic lesion; Thorotrast, [illegible] clinically [illegible] by [illegible].

[illegible] potential carcinogenic hazard to [illegible] animals. However, [illegible] to signal their [illegible].

[illegible] angiosarcoma of the liver in man is [illegible] for all three etiologic agents.

[illegible] years ago, on vinyl chloride gave some indications that this was a hazardous chemical because of its capacity to cause liver and kidney injury, but its carcinogenic hazard was not realized until the

studies of Professor Viola revealed some cancers of the skin, bone, [illegible] in [illegible] though doses of about 30,000 parts per [illegible] per day for five [illegible] did not seem to elicit [illegible] indications that vinyl [illegible] other than the liver in [illegible] possibilities.

[illegible] of oncology in [illegible] confirmed Viola's [illegible] glands [illegible] the [illegible]

[illegible]

[illegible] in their [illegible] laboratories, where

they are doing studies with rats, mice, and hamsters, they have established also that angiosarcomas of the liver appeared in [illegible] through inhalation studies. The NCI project is significant in that liver angiosarcomas in mice appeared in as short a period as six to seven months' exposure at 50 parts per million dose of vinyl chloride, doing a study similar to [illegible] did, five days' exposure as in other studies, and these studies will be carried on for 12 months.

In a test group of about 200 mice -- I'd like to [illegible] that they are 2 out of 200. It's really 40 animals [illegible] of those that [illegible] percentage [illegible] the NCI project is [illegible] period extending to 12 months, [illegible] will be a higher incidence of [illegible] they have exposed at the 50 parts per million level of vinyl chloride, and I'm sure we'll hear about that later from the NCI investigators.

Therefore, data from several laboratories fulfills the requirement for a proven carcinogen in that observations [illegible] several species and strains and that it follows a good dose-response relationship, with some [illegible], showing a response at as low as 50 parts per million.

With a large population of animals carried beyond a seven-months period, as in the MCA study, it might be expected that the over-all incidence would perhaps reach the order of 5 percent. Additionally, it would not be surprising if a response as to liver angiosarcoma would be elicited at levels below 50 parts per million, if we used a larger animal population.

At 50 parts per million exposure level, the time [illegible] of angiosarcomas of the liver [illegible], [illegible] in that long-term continuous exposure comparable in experimental animals to a time frame for human occupational exposure, may reveal [illegible] period perhaps beyond 30 years.

I note on [illegible] that the induction period ranges [illegible] from eleven to about thirty years.

If one were to assume that in a population occupationally exposed to vinyl chloride there were 100,000 workers [illegible] of vinyl chloride, [illegible] polymerization of vinyl chloride to polyvinyl chloride, and fabrication and storage of PVC with [illegible] then perhaps a 5 percent incidence would be most significant for workers at risk.

[illegible] that may arise in non-occupational situations such as polluted air, water, and

previously the use of aerosolized products containing VC as a propellant -- I presume someone will address themselves to this point on the environmental contamination problem, but as an environmental health [illegible], I always indicate that one has to consider several types of stresses. The stress that the individual man or woman gets in the general environment by inhalation of the air, the drinking of the water, and the diet, and, lastly, he gets a compound stress on top of that which is due to [illegible] the exposure in the workplace. That's what I call the total or integrated stress.

Unfortunately, we do not have at hand the epidemiological data relating acute exposure levels to VC with [illegible] [illegible] [illegible] [illegible] parts per [illegible] reported about angiosarcomas of the liver in people not directly involving plant [illegible] vinyl chloride.

Based on what doctors have given, vinyl chloride appears to be a potent hepatocarcinogen. It is capable of inducing non-neoplastic lesions and liver dysfunction, culminating in the irreversible angiosarcoma of the liver. If man responds to low level exposure to vinyl chloride as has the rodent, a low level, continuous exposure of 50 parts per

million for man would have a high probability for inducing liver cancer.

Certainly there is little margin for safety if a response can be expected at a level below 50 parts per million, which in truth is now only a fifty-fold safety factor in terms of the proposed standard. According to toxicological principles, once this compound is a carcinogen, then to establish a tolerance or safe level, there would have to be a 100 to 1 margin of safety in terms of a no-effect level, and from the experimental data on the animals we don't even know yet what the no-effect level is. Obviously, this would put the allowable level at a small fraction of a given standard -- of [illegible] as [illegible] possible [illegible] technological feasibility, a [illegible]

[illegible] production [illegible] other factors that may be associated with exposure to this hepatocarcinogen. Our knowledge concerning the role of associated contaminants in vinyl chloride in the induction of cancer at various sites, especially the liver, is lacking as is the role of dietary factors such as low protein intake and the insult from alcohol

[illegible]

[illegible] a model [illegible] that we [illegible] different thres- hold [illegible] may be very [illegible] animals are [illegible] it may be [illegible]

[illegible] threshold of [illegible] tolerance curve, the [illegible] things that people [illegible] to complain [illegible] known to us as the [illegible] and one [illegible] curve.

[illegible] and is the so- called [illegible] as I say, is called the probit [illegible] probability of an event [illegible] individuals are below that threshold level.

[illegible] of the models in use is the so-called [illegible] logistic model, [illegible] model derived from [illegible] that at very low doses, [illegible] than as the dose is increased,

the response increases very rapidly, and then at very high doses, the increasing number of individuals that will respond [illegible] find that [illegible] in chemical [illegible] in binding theory. In the way [illegible] that there are a small number [illegible] binding sites on the cell which the [illegible] have an effect, and [illegible] up levels indicating that [illegible] all the binding sites have [illegible] the chemical has to go around looking for additional binding sites, so the [illegible] in producing its [illegible]

[illegible] in use, the so-called [illegible] models, which [illegible] a carcinogenic effect, a cell has to be hit by a bundle of energy, a quantum of energy, a bundle [illegible] of that sort, and can hit in enough [illegible] behavior to a [illegible] which goes on in its own [illegible] to the usual controls that [illegible]

[illegible] into a whole group of [illegible] it doesn't take one blow to cause this [illegible] it takes two blows to cause this effect.

these don't give any mechanism in the cell that has to be turned on off or turned on; there are two mechanisms in the cell.

[illegible] of models called the extreme value models, and the kind of problem we're concerned with here is an extreme value problem, what occurs at [illegible] of dosing. [illegible] value models are used in engineering. The engineer needs to [illegible] build a dam so high that the highest flood in a period of a large number of years -- let's say 200 years or 250 years -- will not exceed the height of that dam, an extreme value concept.

[illegible] at the very low doses.

[illegible] the kind of material that's [illegible] That's been found [illegible] with the choice of one of these particular models. The different models give you very different results at the very low dose levels.

The one-hit model, which is the one that's currently accepted for the problem of the induction of cancer through radiation, through atomic energy, give you results down at the

very low levels that are -- give you so-called safe doses, does at the very low levels of exposure that are very much lower than the probit [illegible] -- that is, the one-hit model requires a very much lower dose to be called safe than does the probit model to be called safe.

Several people have attempted to provide some logical means of [illegible] the [illegible] of these models. One of these is my colleague Nathan Mantel, who is now with George Washington University, and in 1961 he and Ray Bryan, a cancer researcher, [illegible] the so-called Mantel-Bryan model, [illegible] as its basic theory the probit dose response [illegible] of the curve -- the [illegible] a so-called guarantee [illegible] your responses have been, let's say, one out of fifty [illegible] out of fifty or something of that [illegible] and they say, "Now, in experimentation, two out of fifty is consistent with a very much larger number having occurred. [illegible] in this particular animal experiment, this is what we have got. Let's be careful and be conservative and accept either a 95 percent upper confidence limit or a 99 percent upper confidence [illegible] and then let us extrapolate down from that level, also taking into account the [illegible] levels." [illegible] extrapolate down from that [illegible] level to whatever level we say is a safe level. From

[illegible]

[illegible]

[illegible]

that the kalami fish wiped around with -- that would be a [illegible] of, I don't say one part per 100,000, and part per million, one part per ten million, one part in one billion, one part in a hundred million.

[illegible] The results of Brown's [illegible]

[illegible] material which [illegible]

[illegible]

of your table, [illegible] label "Risk Level."

[illegible] the first [illegible] should be 1 in [illegible]

[illegible] the next [illegible]

[illegible] hundred million [illegible]

[illegible]

[illegible] the first one will [illegible]

[illegible]

[illegible] fairly steep slope -- [illegible]

[illegible]

[illegible] I had hoped to have [illegible] computations based on Professor [illegible] Postal Service [illegible] is put back to work, the National Institutes of Health computer was having some hiccoughs yesterday and we couldn't do [illegible]

That's not a technical diagnosis: the hiccoughs in a computer!

[illegible] this particular table the [illegible]

[illegible] under the [illegible]

[illegible] thousand; 25 parts per [illegible]

[illegible]

[illegible] thousand.

[illegible] one in a million, [illegible]

[illegible]

[illegible]

[illegible] the median [illegible] in the

[illegible] for a [illegible]

[illegible] one million [illegible]

[illegible]

[illegible] and the same [illegible]

[illegible]

[illegible] similar computations for the data

from the Manufacturing Chemists Association for several

[illegible] the [illegible]

material [illegible] results. As someone who is concerned

with this particular kind of thing, I personally am disturbed

at the very high mortalities that have occurred very early [illegible] and I am concerned about whether one has [illegible] adjustments for these very high mortalities before these computations can be done.

So we have not made these computations.

[illegible]

the [illegible] which indicates that [illegible] cases found in the [illegible] animals than [illegible] would lower all the [illegible] estimates that I have shown, would lower the safe [illegible] safety levels lower than [illegible]

[illegible]

[illegible] people who have been involved in [illegible] problems [illegible] for a so-called "no-effect" level, the level at which no [illegible] sort of building in an engineering safety factor, as it were, and say that then would be a safe level.

From the [illegible] data, that would have

[illegible] measured by the chemical method, 300 parts [illegible]

[illegible]

per billion.

[illegible] a research experimenter who has been [illegible] at the Carnegie-Mellon [illegible] the Union Carbide Company [illegible]

[illegible]

parts

[illegible]

from rags at night to [illegible]

[illegible]

per [illegible]

[illegible] per square

[illegible] basis, a surface measure rather than a weight measure.

There is [illegible] experiment in which converting from [illegible] a large animal on a milligram per kilogram basis has led to some disastrous results.

[illegible] the mouse or the rat, the rodent's circulation is very [illegible] on the time that it takes to circulate [illegible] than it does [illegible]. This would seem to [illegible] the dose at equivalent sites should be more carcinogenic for man than it is for the mouse or rat. It stays in man longer, in terms of how it circulates through his [illegible]

[illegible] in [illegible]

[illegible] at [illegible] lower dose levels, some additional safety factors of the engineering factor type probably have to be added into the information we got from the mouse levels. The mouse and rat levels.

These generally run -- from people saying:

"Well, divide whatever it is you get for the mice or rats by 100...

this method

of industrial exposure for the United States workers [illegible]

[illegible]

[illegible]

[illegible], [illegible] for you, [illegible] done by [illegible]

[illegible] billion, and if [illegible]

[illegible]

[illegible] hundred

[illegible]

I have [illegible] -- if

you [illegible] further [illegible]

parts
[illegible] at 50/ per billion.

[illegible]

[illegible]

[illegible]

To extrapolate then to the level of 50 parts per million, or -- that then is 50,000 parts per billion, 50,000 compared to 250 -- that would bring me, if this particular relationship held, to the level of risks of the order of less than one in a hundred. [illegible] risks greater than one in a hundred.

JUDGE HYATT: All right. Yes, sir?

[illegible] they have been quoting [illegible] other cancer. [illegible] additional expo[illegible]

[illegible] expect a [illegible] they may have additional data.

[illegible]

[illegible] This is the point of the Government research going [illegible] having to do with [illegible]?

[illegible]

[illegible] interested in that [illegible] level [illegible] with many, many animals, [illegible] they are going to perhaps testify here, [illegible] not?

[illegible] Well, that is what they are interested in, that [illegible] -- the shallow part of the dose-response curve [illegible] you [illegible]

[illegible] In other words, this is a large-scale [illegible] level is [illegible]

DOCTOR [illegible]: If there is a safe level.

DOCTOR KRAYBILL: Yes, if there is a safe level.

I would like to state something here. I have this reference now, by Torkelson, Owen and Rowe, and it is in the Industrial Hygiene Reference Book, reported that repeated [illegible] exposures for six months at 200 parts per million [illegible] changes in the central lobular [illegible] of the liver of rabbits.

Of course, they didn't get it in rats, guinea pigs [illegible] got some liver effects, [illegible] liver damage.

MR. [illegible]: Well, I think that -- as I said, we

[illegible]: This gentleman right here.

MR. HECKMAN: My name is Jerome H. Heckman, and I am general counsel for the Society of the Plastics Industry.

Doctor Kraybill, I would just like to inquire as to whether you are familiar with the publication "Food and Cosmetics Toxicology," widely read, I think, by toxicologists?

DOCTOR KRAYBILL: Yes, sir, I am.

MR. HECKMAN: You testified earlier, if I am not mistaken, that -- and I am not sure I'll pronounce these names right, so I'd appreciate your correcting me -- that you would [illegible] repeating the names of the other two known causes of angiosarcoma in the environment?

curve is. They derive from theoretical concepts -- how is a [illegible] a mouse, how is the rat like a man, and in addition, I would hope, as someone who is concerned with the problem of cancer and the problem of preventing it, that I would hope that in the future we need not have cases in man to demonstrate that some material might be a potential risk to man.

So if what you ask would be done, I don't find it necessary. Other people might.

VOICE: Do you have any evidence that suggests that any level below 50 is capable of producing a malignancy of any kind in any species?

[illegible]: [illegible] Yes, the evidence [illegible] I [illegible] them down with the dose response curve, and I fit them [illegible] one of the [illegible] dose response curves, there are levels below 50 which this dose response curve says it will produce these tumors.

The world does not come to an end, 50 is not a cliff. If I have a dose response curve that is going like this, I don't fall off the cliff at 50. It will continue.

There is a nice thing about nature, there is some continuity in smoothness, and things of that sort. That is what I am depending on, by the way; I am depending on the continuity of nature.

VOICE: I understand you spoke at the meeting in

[illegible] data due to the further verification that [illegible] available, an [illegible] cartridge [illegible] [illegible]

[illegible]

[illegible] observed leakage is no [illegible] [illegible] carbon-supplying [illegible] [illegible] to [illegible] [illegible]

[illegible] methods and data that [illegible] [illegible] [illegible] than that [illegible] [illegible]

[illegible]

[illegible]

[illegible] full [illegible]

[illegible] chemical [illegible] [illegible] oxygen [illegible] but [illegible] the [illegible] will not maintain [illegible] all [illegible] in the [illegible]

supplied-air respirator, if he loses his air supply for any reason, [illegible] he would have to jerk it off, and would he lose his life in some concentration immediately dangerous to life?

This has now been applied to materials, perhaps [illegible] and certainly like Plutonium 239, that have a long-delayed effect. I was a member of the committee that [illegible] American National Standard [illegible] in which it is noted that very high concentrations of Plutonium may be immediately dangerous to life.

I note this only because this is the basic classi- [illegible]

[illegible]

[illegible] later recommendations for respirators for protection against [illegible] that one part per billion of [illegible] is not immediately dangerous to life on a [illegible] basis, be it five or 30 years.

How practical is it [illegible] in these devices? Let us speak [illegible] to self contained breathing apparatus described there are three devices approved for 30-minute life that fall in the category of self-contained breathing apparatus pressure-demand type [illegible] open circuit.

Two of these devices are available with choice by the [illegible] to choose [illegible] pressure-demand with positive pressure in the facepiece, or demand which means a negative

pressure in the facepiece.

The other manufacturer has a device that is avail- [illegible] to insist you wear only positive pressure in the face [illegible], the wearer should not have the [illegible]

[illegible]

[illegible] an adequate number for use in industry, as proposed.

[illegible] cost [illegible], depending on the [illegible]

[illegible]

[illegible] instances, for example, [illegible] they did have [illegible] breathing apparatus. They were highly trained [illegible] should work only 30 minutes [illegible] would [illegible] to do [illegible] of course, [illegible]

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[illegible] the self-contained breathing apparatus.

[illegible] would be fatiguing. Certainly [illegible] from 25 to 35 pounds. The unit, as I [illegible] requires extensive training; the Bureau of Mines, of course, trained,
s [illegible] which covers many days of a training course [illegible] use the device approved for the [illegible] -- not just because the devices [illegible] by the Bureau of Mines as auxiliary devices, not for mine rescue, but they do require quite extensive training.

[illegible] requires extensive maintenance.

[illegible]

[illegible]

[illegible] such as San Francisco Fire [illegible] their own maintenance [illegible] this type of work.

[illegible] would [illegible] that they would have very poor [illegible] with the 30 [illegible] pound self-contained breathing apparatus. Some will refuse to wear it, some will have claustrophobia. In our tests of 90 firemen which are test [illegible] all types of self-contained breathing apparatus -- and these were even trained firemen, when they would put on a device that they were not familiar with, they [illegible] would get claustrophobia.

So I am suggesting perhaps one percent of the people that would be required to wear these simply could [illegible]

[illegible] reasons.

[illegible] have been asked how long they could wear these devices without excessive fatigue. I am not aware of any [illegible] I would point out that [illegible] insist that manufacturers come [illegible] that [illegible] of lowering breathing resistance.

[illegible] because of the excessive [illegible] do to [illegible]

[illegible] goals [illegible] in this [illegible]

[illegible] would [illegible] types of devices [illegible]

[illegible] the [illegible].

[illegible] have any [illegible] this would bring on a workman over a long period of time.

There is another area I would like to comment on; this is relative to subsection on [illegible] 1, paragraph 4, [illegible].

[illegible] that for mainten-

[illegible] chemical cartridge respirators [illegible] air-purifying respirators [illegible] to indicate [illegible] service life.

[illegible] earlier, for example, [illegible] correction; 3.8 [illegible] I would [illegible] cartridges [illegible] and [illegible], was tested [illegible] solvent in 77 minutes, as [illegible]

[illegible] service life is [illegible]

[illegible] and AEC supported research at [illegible] until July 1, '73, on over

quanti[illegible] tests to determine the face-piece leakage [illegible] this indicate, based on face-fit, the half [illegible] for all face sizes and [illegible]

[illegible] factor of [illegible], with a [illegible] face-piece. The protection factor is [illegible] discussion, and I did [illegible] Section [illegible], subparagraph 7.

[illegible] that results to be ordered shall first be [illegible] concentration of [illegible] protection [illegible] [illegible] equipment.

[illegible] is going to [illegible] protection factor [illegible]

[illegible] the teeth indicated, [illegible] protection factor [illegible] with a [illegible] pressure of the [illegible]

[illegible] the face, has an over-all efficiency [illegible] efficiency. This will have [illegible] with a positive in the face-[illegible]

[illegible] of the protection factor, which is [illegible] protection factor of [illegible] [illegible] breathe the [illegible]

This gives an indication of its use

All right, with these qualifications the basis of my recommendations, my recommendations are as follows -- and they are broken into three basic categories:

For protection up to 100 parts per million of vinyl chloride; then I will give those for protection up to 1,000 parts per million of vinyl chloride; and then for protection in concentrations greater than 1,000 parts per million of vinyl chloride.

The first category, for protection up to 100 ppm VC, this is assuming the detection limit of one ppm -- one type C supplied-air respirator demand type, with full face-piece.

Because of the toxicity of vinyl chloride, I do not think that a half-mask face-piece should be used with a negative pressure. This applies to many other highly toxic materials which, if you're interested, later I can give examples. So only full face-piece.

Item 2. A combination type C supplied-air respirator, demand type, with full face-piece and auxiliary self-contained air supply.

Item 3. Open circuit, self-contained breathing apparatus, in demand mode, with full face-piece.

All of these full face-pieces with protection back to 100, therefore they have to be limited to use up to 100 ppm

[illegible] detection limit of one.

[illegible] and don't ask me any questions

[illegible] in the standard and

[illegible] extrapolations thusly. If it is something else,

[illegible] extrapolated. I am giving mine on the

[illegible] basis on the respirators.

[illegible] second classification is for protection

[illegible] parts per million of vinyl chloride.

[illegible] combination type [illegible] supplied-air respirator,

[illegible] full facepiece, with auxiliary

[illegible] air supply.

[illegible] open-circuit, self-contained breathing

[illegible]

[illegible] Your Honor, I do think I skipped a

[illegible]

[illegible] was for protection up to 100

parts per million, and I was indicating the second one for

protection up to 1,000 ppm, and I believe I was reading

[illegible] 1,000 ppm. I apologize, and I will

[illegible]

[illegible] protection up to 1,000 ppm of vinyl chloride,

[illegible] continuous-flow, with half-

[illegible] helmet or hood. This is a

[illegible] positive pressure at all times

[illegible] should have been for protection

greater than 1,000 ppm of vinyl chloride. This has also been interpreted for protection in unknown concentrations for entry into tanks or limited-egress situations. And I did read those; if you missed them, I could read them later.

I would like to note that if a sorbent has been or is developed that effectively sorbs vinyl chloride with an adequate service life, the goal I would look for would be, say, eight hours' service life at 200 parts per million. Then I think that one can consider, as far as our air-purifier respiratory protective devices, such as a full-face gas mask, chin-style, lower back or front-mounted canister with full face piece.

One could consider a combination type C supplied-air respirator, demand type, pressure-demand or continuous-flow type, with full facepiece and air-purifying sorbent cannister.

I note this because if this respiratory protection is required at all times, there are always work situations where the workman must move from one level, from one station to another, at great distances, and he must disconnect somehow his airline respirator, whether it is positive pressure or whether it is negative pressure, and have protection while he is moving.

The No. 2 device recommended in the standard, of course, contains that auxiliary air tank, with a ten-minute

supply

Availability of that device has only been, by the one company that has approval on that, a hundred of them made, and it costs about $450, there will be two years' delivery time on that. I note this because of the importance of considering the sorbent if one is available.

A man could still disconnect the airline and breathe through a sorbent, if you had an efficient sorbent, and move to his next work station.

As it is now, he would have to wear pressure-demand, supplied-air respirator, with an air cylinder with only a limited ten-minute supply. This would have to be changed many times during the day.

In addition, one other point I would like to note:

If a satisfactory quantitative man-test system would be used by the operators, by the manufacturers, for example, for testing the efficiency of the face fit, that is, leakage under simulated work-condition exercises, to assure leakage less than one-tenth percent, devices with negative pressure and a full face-piece, I believe, could then be used for protection up to 1,000 parts per million of vinyl chloride.

What I am proposing is quite different, and is only used now by many of the AEC contractors, that is, that you don't just run a simple fitting test, which is many steps above what most industries do, to send the man to the tool-

JUDGE MYATT: All right.

Mr. Klein, do you have any questions?

MR. KLEIN: I have just a few, Your Honor.

Mr. Myatt, directing your attention to the size of the face-pieces, do all manufacturers make the same size face-pieces, or would that vary from manufacturer to manufacturer?

MR. MYATT: No, sir, they do not all make the same size. This information was in a paper that I presented in '71, published in AIHA Journal on the respirator efficiency testing with DOP.

We specifically pointed out half-mask face-piece sizes, in fact we compared them, and the only anthra-metric data known and published has been by the Air Force. Air Force oxygen masks. Take the basic, large, medium and small, which is comparable to a half-mask face-piece, fitting over the nose and under the chin. You will see that one size sold is comparable to the large size Air Force oxygen mask. Another one, comparable to the small size.

One, a very good one, is comparable to the medium; and one is quite different than anything else, is quite wide, a half-inch wider than anything made. This would cover a large mouth like mine; when I smile, in some of these masks you can see my teeth. Obviously that would leak.

Each one approaches it differently, and tries to

come out with the best designed face-piece that he will think one size will provide the protection for the largest number of individuals.

MR. KLEIN: Would there be small, medium, and large, full-face and half-face respirator masks available at this time?

MR. HYATT: No, sir, not at this time. This type of information, which NIOSH which has sponsored, the reports are available, research on developing this for the future work, Webb & Associates, for example, in working with Los Alamos; there's been a report published on the proposed test panel.

So that men and women, [illegible] is [illegible] of at least 95 percent of the face size and shape of the working population in the U.S.

This is in the future. It is anticipated that this amendment to permit this will be published. Then the manufacturers are going to have to have some time to then design two or three sizes, whatever they think. The current thinking is that they will let them come up with sizes to fit all men, all women, and only 95 percent of those.

MR. KLEIN: Are there respirators that fit well, described as a typical size face, today?

MR. HYATT: There are respirators to fit the typical size face. But there are no tools or ways to select the device in

requiring the use of respirators on all coke ovens at all steel plants. And they require these eight hours a day These are half-mask air-purifying respirators they are using now.

There is an instance of using them continuously during their entire workday and workweek.

There are instances where men are wearing supplied-air respirators, where they are doing, for example, grinding or cutting on lead, or lead-contaminated material, for long periods of time.

The only way you are going to approach your answer is to pick out certain types of industries, where some of these devices are used, and then each industry is going to vary.

So, are they worn continuously? I really don't have the answer on that, only industry, by each type, and each type of device. You see, I know of no one wearing a self-contained breathing apparatus continuously, except where there has been a major accident. And I noted the incident of the fire, with Plutonium exposure.

The only thing available, and the concentrations were so high that they were immediately dangerous to life, was a self-contained breathing apparatus. They did wear it for many weeks. There was no choice.

But they only wore them about two hours in the

morning and two hours in the afternoon, and they had two crews, for example, to do the work.

MR. KLEIN: Now, in your testimony you indicated that between 100 parts per million and 1,000 parts per million, you would recommend a one-half face-piece. But, under 100 parts, you recommend a full face-piece. Could you explain the reason why?

MR. HYATT: Pardon me, if I gave that impression, I sure didn't mean to. I would like to come back and say that -- I must ask you first: Are you referring to air-purifying demand type, with a negative in the face-piece?

I would like to re-emphasize, for any supplied-air [illegible] mode, I would not recommend anything but a full face-piece.

Now, if you're referring to -- and I did say a combination supplied-air respirator, continuous-flow type, with a half-mask with a full face-piece suit, or hood -- yes, this was in the category of recommending for protection up to 1,000 times.

MR. KLEIN: Yes. Could you -- I glean from that, that you did recommend a half face-piece. Is that right?

MR. HYATT: Yes. On the basis that there is a positive pressure at all times, and unless eye protection is needed from, for example, the atmosphere, a half-mask can be fitted and used with positive pressure, and give as good a

protection as a full face-mask. It is simply not as stable on the face. This is some that those in charge will know which one is adequate and satisfactory for the individual use.

MR. KLEIN: Let's talk about the compressed-air, when you're requiring a continuous-flow --

MR. HYATT: Oh, yes.

MR. KLEIN: Do you have any recommendations with respect to the sources of compressed-air? In other words, would you recommend taking from the ambient air?

MR. HYATT: A very good question. And I did mean to bring that out. There is a requirement, of course, under OSHA's use and regulation respirators, specifying air quality. And this, for example, Grade D air under compressed-gas association standard, G-7. But no place in there does it say anything about vinyl chloride. It limits CO, it limits other materials, but Grade D even allows 20 parts per million of CO, carbon monoxide.

I recommend on a Grade E, and I understand OSHA is considering this, because 10 parts per million I think should be the limit.

Now let's come to air quality. There's two considerations here. One is, first, for supplied-air respirators, whether it is a continuous-flow type or a demand type. And you have to consider, of course, the number of men. It takes

a very large amount of air. There has to be a large compressor -- compressors are available -- with a large holding tank, in case of power failure, that the men will have time to escape.

This is going to create a problem, because that compressor is only going to compress the air which surrounds the compressor. And if you don't have sorbent sufficient enough to use air-purifying respirators, I don't know whether we would be able to purify the air enough without locating it upwind from the plant at some distance, and I certainly think that the limit of vinyl chloride in compressed air should be less than any limit that is permitted, for example, in the workroom.

And a rough guideline is only -- always been approximately ten percent. If we're looking at one part per million detectable, I'm suggesting, now the air is one-tenth parts per million would be the maximum permitted in breathing air.

The other major category simply is self-contained breathing apparatus, having their tanks full. They can do this with a compressor. This is available from commercial sources, many companies are providing compressed-air, washed-air, or they are making synthetic air from liquid oxygen and nitrogen.

MR. KLEIN: Do you know about the availability of

other companies, other than Mine Safety Appliances?

MR. HYATT: No, I have not. I have attempted to, in the short time -- I have only known for three days that I was coming here to this hearing; there was an indication a few days earlier, but that really didn't give me time to make these contacts.

MR. Do you have any recommendations as to what would be appropriate in the interim, while we're waiting for the two years to receive these space suits?

You're not certainly suggesting that we go out of business for two years, are you?

MR. HYATT: No, sir. I'm suggesting, and I have made some recommendations [illegible] to consider the use of supplied-air respirator, continuous flow, or demand type supplied-air respirators.

These are much more available commercially.

And the other device is the self-contained breathing apparatus, for example.

I have no estimate. These are used by the tens of thousands compared to maybe a maximum of 10,000 self-contained breathing apparatus now used by the fire departments. This came from an estimate of converting from demand to pressure demand, I am not sure, others may have better figures.

MR. Have you had an opportunity to

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look at the reactors that any of the companies own?

MR. HYATT: No, sir, I have seen no reactors and I have never seen a process, where vinyl chloride is manufactured, processed, or anything else.

MR. You could not then make any comment on the safety factors that might be involved in using a back-pack or a long cord; is that correct?

MR. HYATT: Right. I can only comment, not from firsthand, on what I know the situation is, and what anyone selecting -- and that is that one must very definitely take into account the activities of the wearer and the safety factors. These are -- has to be considered.

MR. Do you think a space suit is practical if an individual employee is going up and down stairs or working long distances away from where the air is supplied?

MR. HYATT: Of course you're going back and forth between self-contained and space suit -- by space suit, I assume you mean a supplied-air suit?...

MR. Right.

MR. HYATT: There's some resemblance to a space suit, certainly they are a lot cheaper.

But no, it is not a very practical device, where a man moves great distances, there's no question he has to disconnect.

MR. Do you think it's practical for

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4. Exposure Levels.

which are under way.

Immediately following the report of January 22, NIOSH and its parent agency, the Center for Disease Control, organized a surveillance network to determine the number and distribution of cases of this rare disease and its relationship to occupational exposure to vinyl chloride and/or polyvinyl chloride.

The detailed results of this activity are shown in the table which is attached to my presentation. Table 1.

Thus far, 18 cases of angiosarcoma of the liver in polyvinyl chloride production workers and one case in vinyl chloride monomer production have been confirmed. Thirteen of these cases were reported from the United States and six from other Countries. All thirteen of the U. S. cases and the one from Great Britain, have been confirmed histopathologically by the National Institutes of Health. Ten of the U.S. cases are deceased; three are living. The distribution of cases from the United States and four other Countries indicates that we are observing a newly recognized occupational disease associated with exposure to vinyl chloride: angiosarcoma of the liver. This form of liver cancer has heretofore been quite rare in the general population -- only twenty to thirty cases have been reported annually in the United States.

The greater number of occupational cases seen in the United States is probably a reflection of the earlier initiation and greater intensity of surveillance activities here

As regards the distribution in the United States, we have seen that the thirteen cases have been reported from a number of plants in different parts of the Country. These include seven cases from the B. F. Goodrich plant at Louisville, Kentucky; three cases from the Goodyear plant at Niagara Falls, New York; two cases from the Union Carbide plant at South Charleston, West Virginia, and a single case from the Firestone plant at Pottstown, Pennsylvania. Although we are aware of several factors, such as job duties and degree and length of exposure, which may account for differences in occurrence, too little information is available at this time to evaluate such differences.

The average age at death for the PVC production workers was [illegible] years, which is about seven years younger than the average age at death from liver cancer in the male population of the United States. The estimated latent period for this disease based on the experience of the eighteen PVC production workers is on the order of twenty years. This is consistent with observations of other occupational cancers with latencies varying from fifteen to twenty-five years.

Within the past two weeks, we have also identified two deaths from angiosarcoma of the liver in men employed at plants using polyvinyl chloride to fabricate other products. A summary of the surveillance activities in Connecticut, which led to the discovery of these cases, is given in the CDC Morbidity

and Mortality Report for the week ending June 28, 1974, which is also attached to the copy of my presentation.

Although we have concentrated our efforts to identify and evaluate the cases of angiosarcoma of the liver, it will be several months before we can expect to complete this activity.

The evidence accumulated to date on the cancer experience of the polymerization workers, along with the evidence of induction of the same unique tumor in two animal species exposed to vinyl chloride down to and including fifty-parts-per-million, is convincing evidence that these liver tumors resulted from exposure to vinyl chloride.

[illegible] and epidemiologic activities of the past few months, we have become aware of other possible health effects of exposure to vinyl chloride. Of major importance among these is a disabling liver fibrosis. This condition, independent of angiosarcoma, has been noted in workers from one of the United States plants and has been observed in almost a third of the men working in one of the German plants. This condition has also been noted in most of the U. S. cases of angiosarcoma of the liver associated [illegible] production. It is not yet known whether the fibrosis is a precursor of angiosarcoma of the liver; or to what extent it occurs among workers exposed to vinyl chloride. Clinical descriptions of several of the

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there is a distinct possibility, from looking at their data, that we may see malignancies other than angiosarcoma of the liver in this population.

110

MR. KLEIN: Your Honor, in light of Dr. Key's request with respect to Mr. Lloyd, I would prefer not to ask further questions at this time, and allow Mr. Lloyd to answer any questions from the audience, and then he could leave.

JUDGE HYATT: All right. Yes, sir?

MR. TOPOL: If I may, please.

With regard to the cases of angiosarcoma in the United States, these cases have been reported among employees in 13 different plants; is that correct?

DR. LLOYD: No, at four different plants, to date.

MR. TOPOL: Four. It's 13 employees at four different plants in the United States?

DR. LLOYD: At four polymerization plants. And two cases to date from plants engaged in fabrication.

MR. TOPOL: Concentrating on the ones that have been developed at the PVC plants, how many plants are there in the United States that are 20 years and older?

DR. LLOYD: I don't think I could give you that number. I know there are 37 plants in total. I think the plants that we have seen this from so far as the plants that have been on line the longest. But even in the case of those plants, we have yet to track down the total population. So I don't know what we can

vinyl chloride or polyvinyl chloride.

DR. LLOYD: I don't think you're quoting us correctly on that. I think Dr. Key pointed out that the information on the two cases is insufficient to say what the extent of the problem could be among the fabricators. We do point out that having seen the persons exposed to vinyl chloride are showing a very high rate of this disease, we now have begun to identify people who might have had considerably lower exposures than this initial population.

114 Both of these cases were confirmed at the National Institutes of Health, as angiosarcoma of the liver. Both of these men worked in environments where there would have been exposure to vinyl chloride.

What we say at this point, we are not willing to say how serious the problem could be in fabrication; we want more evidence.

MR. HECKMAN: In other words, you're not denying this part about morbidity and mortality weekly report, also submitted with Dr. Key's testimony, to the effect that no causal connection has been established between those workers in the fabricating plants and the PVC?

DR. LLOYD: I don't think we say anything about causal connection. I think we did say that the evidence at hand shows that vinyl chloride induces angiosarcoma of the liver.

Here is a population that had low exposure to vinyl

chloride, and here is the evidence to date on the health effect. We do not know what the extent of the problem is yet in fabrication.

MR. HECKMAN: Well, in this report that's attached to Dr. Key's statement, it's indicated that, with regard to these two other cases, the findings establish no causal connection between exposure to PVC and angiosarcoma of the liver.

I can assume that that is a part of the testimony, and that the inclusion of these two cases in the table is not intended to indicate a causal connection, despite that statement. Is that correct?

115 DR. LLOYD: If I can try to interpret for you what they are saying in that report.

MR. HECKMAN: I'd appreciate it.

DR. LLOYD: They're saying in this specific case, in the single individual case, if a person dies of angiosarcoma of the liver, he could have been exposed to many things. He could have been exposed to thorotrast, to arsenic, to other things that might have caused this disease. We have recent evidence that indicates that vinyl chloride produces these tumors in great number. And part of the development --

MR. HECKMAN: In great number?

DR. LLOYD: In great number, very great number for this population.

When you're looking at a disease where you would only

see 20 or 25 deaths from this disease in a year in the population in the United States, and we have now have identified in the United States alone 15 cases associated with this kind of exposure, I think this is a very, very serious problem. This is a great response.

MR. HECKMAN: Do you believe that that could in any degree be possible, to the fact that looking for angiosarcoma in the past, in the general population as well as among PVC workers, may have been a bit less intense?

DR. LLOYD: We have no evidence that any recent looking for cases would have brought this out.

MR. HECKMAN: Well, I'm not certain -- if this is one to be directed to you, I assume you will tell me, and I will sit down and wait to direct it to another witness.

But are you in a position to inform us as to whether or not it's common practice for the medical profession to

116 examine patients who have died of liver disease on an in-depth basis to determine whether or not the disease may have been angiosarcoma?

DR. LLOYD: I don't know how germane that might be, but we do know that, for a number of these deaths, there has been mis-diagnosis and mis-reporting of cases.

MR. HECKMAN: And that could be true for the general population as well?

DR. LLOYD: Oh, yes. Yes.

MR. HECKMAN: In other words, it's quite possible that many deaths from liver disease, which are diagnosed as cirrhosis, necrosis, general hepatoma, or any similar liver ailment, could conceivably involve angiosarcoma, if the investigation were intense enough?

DR. LLOYD: I can only say my impression from the people I have talked to is that that wouldn't be a great number. Perhaps instead of 25 you might have 50.

MR. HECKMAN: But that is a possibility?

DR. LLOYD: Oh, yes. Sure.

MR. HECKMAN: Are you familiar with the techniques necessary to determine whether you have got angiosarcoma or not?

DR. LLOYD: No, you'd have to talk to a pathologist on that.

117 MR. HECKMAN: Okay, then that eliminates your part of the questioning. Thank you very much.

[Announcement.]

JUDGE HYATT: Yes, ma'am.

MS. HRICO: Andrea Hrico from the Health Research Group.

Dr. Lloyd, you mentioned the industry-sponsored mortality study done by Tabershaw and Gaffey. Do you know if that study was strictly limited to plants where workers were first exposed to vinyl chloride more than 20 years ago?

DR. LLOYD: No, they don't identify the plants. They

do say that in the total population that they had, of 8,384 men, there were only 855 who had had 20 years or more exposure.

MS. URICO: So about a tenth of those workers, then, had more than 20 years' exposure.

In a study like this, aren't the results diluted by including workers who exposure is less than 20 years ago, since the latency period for development of cancer is 20 years? For development of the angiosarcoma.

DR. LLOYD: Yes. Yes, we're looking at a disease with a 20-year latent period, and most of the men included in the study didn't get up to 20 years, in order for the disease to appear.

MS. URICO: If a PVC production plant that is less than 20 years old does a survey of their workers and reports that there is no evidence of increased incidence of angiosarcoma of the liver among their workers, can any scientific judgment be drawn on that data of the plant, if the workers have been exposed for less than 20 years?

DR. LLOYD: As a possible cancer response, I'd say no, you couldn't draw a judgment.

MS. URICO: I have one other question.

With respect to the average latency period of 20 years for the development of angiosarcoma of the liver, would you please comment on the length of time you would recommend to keep medical records on exposed workers?

DR. LLOYD: Well, the average latency is 20 years; but if we look at the fabricator whose death may have been induced by vinyl chloride at a very low exposure level, he had a 36-year latency. And while the average is 20, it will vary on both sides; the shortest has been 20, the longest has been 36.

I would say we're going to want to keep records for 30 years or longer.

MS. HRICO: So you would recommend that change, then, in the OSHA Proposed Standard, which is now 20 years?

DR. LLOYD: Yes.

MS. HRICO: Thank you.

JUDGE WYATT: Are there any other questions of Dr. Lloyd? Yes, sir. Identify yourself, please.

MR. ROWLEY: My name is Rowley, of Mercury Plastics in Middlefield, Ohio.

Did the two fabricators involved also mix or compound their own material?

DR. LLOYD: We have only very limited information because our people haven't been in to the plant yet. I can tell you very briefly the information we have.

One man worked most of his career at a machine where they were extruding electrical wire covering with a PVC plastic. The mixing of the plastic material was on the floor above him. It's my understanding that they have measured vinyl chloride on that floor up to 16 parts, and I have heard that they were not

able to measure vinyl chloride in the immediate work environment where this man had worked.

119 The company did point out that there are temporary assignments at this plant, where it may not be recorded in the man's work history, and he could have worked in different areas of the plant.

In the second case, the man was employed at a plant producing a vinyl fabric. He worked there as an accountant. It was known that he went in and out of the plant occasionally. Because of the fact that he only worked there ten years, we are looking back further in his work history to see if there's a possibility of an exposure to vinyl chloride at an earlier point.

MR. [illegible]: Have you monitored any plants that you know are fabricators, and didn't mix at all anywhere in the plant?

DR. KEY: Yes. I reported on levels in seven of these in my testimony.

DR. LLOYD: But I think he's asking about vinyl fabric.

JUDGE [illegible]: Well, it's apparent that you are going to have to ask that question of someone else, other than Dr. Lloyd.

Are there any other questions?

There being none, Dr. Lloyd, you are free to go.

Mr. Klein, do you have any questions of any other members of the NIOSH team?

MR. KLEIN: Yes, I do, very briefly, Your Honor.

126 Sealing. Could that possibly be an OVA or a total hydrocarbons figure rather than a VCM figure?

MR. JONES: No, it -- I am James Jones, industrial hygienist with NIOSH.

No, this is a VCM figure. It was taken by means of collecting a 250-milliliter atmospheric sample in a glass gas-collecting tube, and returning this to the laboratory for analysis by gas chromatography.

MR. HECKMAN: Right. Do you have any explanation for why this result is so different from all the others? Is this just a random happening?

MR. JONES: Well, this is in a different plant than the others. These results are all the result [illegible] a very brief survey, just taking a few samples in each plant in order to have some idea of what levels were present. It's by no means a definitive survey of these particular plants.

MR. HECKMAN: Right. In other words, you don't feel that this table necessarily establishes a close link between fabrication plants and angiosarcoma of the liver?

MR. JONES: I think definitely that you find levels of vinyl chloride, as typified by these figures, in fabricating plants, both from our own measurements and from information we have obtained and discussed with manufacturers.

MR. HECKMAN: The most typical figure being .3,

127 according to this table -- or less than?

of the U. S. cases confirmed by the two top experts in the country.

MR. HECKMAN: These were the vinyl chloride cases?

DR. KEY: Yes, but as Dr. Lloyd pointed out, even though you admit a several-orders-of-magnitude mistake, or under-reporting of angiosarcoma of the liver in the general population, a clustering of this degree in a work population is extremely
129 suggestive that there is an occupational relationship here.

MR. HECKMAN: Well, we're certainly not suggesting that it be ignored, it's just that it begins to irritate after a while to keep hearing this referred to as an extremely rare liver disease, when we think perhaps maybe a contribution has been made to the profession by pointing the doctors at the idea of looking for angiosarcoma in general now. And that might be somewhat helpful.

In any event, I think the point is made.

The only other question I guess I did have, Doctor, I'm not sure this isn't a duplication, is: Is it frequent for doctors to differ in their diagnosis of this type of case?

DR. KEY: Quite.

MR. HECKMAN: In other words, one doctor is apt to call something angiosarcoma, and another to disagree?

DR. KEY: Yes.

MR. HECKMAN: Thank you.

JUDGE MYATT: Yes, sir?

MR. SAMUELS: My name is Sheldon Samuels, Industrial Union Department.

I have a question for Dr. Key. In your statement you refer to your memorandum of March 11, 1974, in which you make reference to your inability to describe a safe exposure level.

Is this inability unique to this carcinogen? And is this unique to occupational health?

DR. KEY: I guess the answer depends on your

130 definition of "safe".

According to the one-hit theory of oncogenesis, no level is safe. The government facility at Pine Bluff, Arkansas, is conducting experiments to produce information on the slope of the dose-response curve, and only after the results on these --- and it will take many years --- are available, can we come anywhere near answering your question.

That's why I used another term in my testimony, and that is an "acceptable" level, which gets away from the safeness concept.

No, I don't know what a "safe" level is for vinyl chloride, and I suppose this would apply for other carcinogens as well.

MR. SAMUELS: The second part of the question was whether this principle, which you've described, is unique to occupational health. Isn't it true that in other areas of public health, food and drugs, et cetera, we have the same problem, and

5. Expose the wet with PVC plastisol fabric to elevated temperature to fuse the liquid plastisol into the solid state.

In those manufacturing operations, we make no chemical change in the identity of the polyvinyl chloride resin we obtain from the PVC resin producer. We make physical changes by processing it into a liquid plastisol and subsequently into a solid state. The extent to which our manufacturing operations experience exposure to vinyl chloride is obviously dependent on the residual amounts of vinyl chloride in the polyvinyl chloride resin we receive from our resin suppliers.

There is a potential amount of vinyl chloride present in the atmosphere around several points about the above outlined unit operations as a consequence of residual vinyl chloride in the PVC resin. The points at which there is a potential amount of vinyl chloride are:

1. Where the bags of PVC resin are stored.

2. where the bags of PVC resin are opened and dumped into the mixer for making the plastisol,

3. over open-top plastisol mixers,

4. where the exhaust from the vacuum pump that removes air from the plastisol vents to the atmosphere,

5. around open storage and dip tanks of plastisol,

6. in the fumes from the oven in which the liquid

plastisol in and on the fabric is fused into the solid state, and

7. around the PVC conveyor belt leaving the fusing oven.

Appropriate ventilation, we all quickly conclude, reduces the potential presence of vinyl chloride around the above mentioned points.

The exhaust from the vacuum pump should be vented outside the occupational area; for, air, beaten into plastisol during the mixing action, when evacuated, may also be accompanied by vinyl chloride gas.

The very substantial draft in the fusing oven re- [illegible] plastisol temperatures in the oven and also removes any occluded vinyl chloride that may be released at the elevated temperature before the PVC plastisol gels and fuses. The draft is pulled from the openings in the oven where the fabric enters the oven wet with plastisol and leaves the oven with the plastisol converted into the solid state. The exhaust from the fusing oven should, of course, be vented outside the occupational area.

Both specific area sampling and personnel monitoring and gas chromatograph analysis for vinyl chloride under the guidance of a graduate biologist with six years of industrial hygiene experience have been pursued in the typical areas of

through [illegible] sensation--that we might be dealing not [illegible] [illegible] of some 1500 vinyl monomer workers and some [illegible] polymerization workers, [illegible] with conceivably many hundreds of thousands of polyvinyl production workers and possibly exposed to varying levels of residual vinyl chloride monomer [illegible] so.

[illegible] we have learned from beryllium, we have learned [illegible] that the hazard might not stop at the [illegible] workers' homes and [illegible] neighborhoods about vinyl chloride-polyvinyl chloride [illegible] and that transport and storage might present [illegible] risks.

[illegible] which I have [illegible] are [illegible] to control vinyl chloride hazards. However, [illegible] health hazards, [illegible] the monomer [illegible] polymerization [illegible]

It is unlikely that the [illegible] which enveloped vinyl chloride toxicity for 25 years will in any way continue, [illegible] research won't be done, that few studies will be made. [illegible] of the University of Bonn, speaking at the New York Academy of Sciences meeting on May 10, found it [illegible] remarkable [illegible] than the [illegible] report of [illegible]

in 1949, in more than 25 percent of a group of vinyl chloride workers, was only marginally mentioned subsequently. We just didn't do our homework, we didn't do our research, we didn't all of us do what we should have done on the basis of the reports that were filtering through.

Perhaps the most graphic description has been in the title in a leading article in the British journal, New Scientist, for June 13, 1974, which read "Science paused--and 17 died."

The central issue then is control and elimination of vinyl chloride health hazards, particularly the neoplasms that have been discovered associated with vinyl chloride [illegible] it is likely that many aspects of the problem will be examined, discussed, debated, argued and so forth. I suggest that the relevance of these debates and contributions be measured by whether or not they add to the likelihood of hazard control, by whether they provide an additional margin of safety or subtract from it.

During the past four months, since the beginning of February, my colleagues and I at the Mount Sinai School of Medicine have initiated a broad program of vinyl chloride-polyvinyl chloride research. These have ranged from studies of vinyl chloride transport in the blood. Dr. Oster in our laboratory has demonstrated that the vinyl chloride becomes

documents I have mentioned, I would like to summarize some of our findings in these 354 workers.

First with regard to peripheral vascular disease. In 1957 and 1958, Filatova and colleagues first pointed out what they called a "toxic angioneuropathy" in vinyl chloride workers, with another report in 1965 detailing a Raynaud's-like syndrome. Numbness and tingling of the fingers, along with increased sensitivity to cold, were early symptoms. We have confirmed the importance of these findings. Among the [illegible] workers, [illegible] percent, had numbness or tingling, with excessive sensitivity to cold being found in 63, or 18 percent. However, the typical Raynaud's syn-

[illegible] vinyl chloride toxicity findings. The prevalence of Raynaud's syndrome was significantly higher among workers with more than 10 years of exposure. Similarly, an abnormal Allen test, indicating delayed arterial circulation in the areas supplied by the ulnar and/or the radial arteries, was found in 56, or 15.8 percent, of the examined workers.

Acroosteolysis. Generally, in scientific meetings, you hardly hear anything other than acroosteolysis, and I have hardly heard it all day today, which is probably just as well. Now, we are unable at this time to provide clear information concerning the incidence of typical acroosteolysis in this group, since many of the X-rays of the hands

and four have but recently reached us. And they are being read for us by our experts in our X-ray department, and this takes time. We might note, however, that pseudo-clubbing of the fingers was prevalent in 6.7 percent clinically; in the group with more than 20 years of exposure, it was 17.3 percent.

[illegible] skin changes were found in [illegible] of the examined workers. Perhaps reflecting access--you will notice how cautious I am now--perhaps reflecting access to different clinical [illegible], it should be noted that the [illegible] characteristic skin changes of edema, thickness, stiffness, decreased elasticity, much less frequently than did the [illegible]

[illegible]. [illegible] we did not observe the [illegible] [illegible] changes [illegible] described by the German group. I [illegible] [illegible] explanation for this. We just didn't see as much in [illegible] as the German scientists reported.

[illegible] hypertension. This has also been reported, primarily by Russian scientists, as being a finding of increased frequency among VC-PVC workers. It was not so in our study population. We didn't find any excess of hypertension among the people studied by us. Abnormal urinary findings were also not prominent. In particular, I would mention that gross hematuria was absent and microscopic

[illegible] enlargement. I consider this a happy find [illegible]

[illegible]

animals included in this studies.

Liver disease. The liver was found to be slightly enlarged [illegible] in 18 percent of all the [illegible]

[illegible]

[illegible] than was [illegible]

[illegible]

and [illegible] palpable, [illegible] enlarged spleen [illegible]

[illegible]

[illegible] Bromsulphalein [illegible] positive [illegible] liver function tests. Now, the percentage [illegible]

the bilirubin was greater than 1.1 milligrams in 6 percent, [illegible]

[illegible] alkaline phosphatase, however, was found to be

elevated in an important number of workers, 16.6 percent overall. This ranged from 12.6 percent elevated among those with two years or less of exposure to 25 percent with elevated levels in the 20-year and over group. When an enlarged liver or an enlarged spleen was present, 41 percent showed increased alkaline phosphatase levels.

We sought to determine whether alcohol intake might have an important relation to these unusual findings; and we found that 1/[illegible] of the cases with clinical evidence of liver or spleen enlargement, there could have been a factor of alcohol and, further, in about 1/[illegible] of those with increased alkaline phosphatase levels, there was a history of significant intake. There may indeed be a multiple factor interaction that should be considered.

[illegible] Pulmonary disease. In 19[illegible], Szende and colleagues reported pneumoconiosis in a worker exposed to PVC dust. Our examination included careful clinical examination of the chest as well as detailed pulmonary ventilatory function studies and chest X-rays. Abnormalities were found, but at this time the nature of the defect and its importance are still unclear.

In a review of the first [illegible] chest X-rays, 27 percent were found to show some abnormality. In general, these were nonspecific linear, reticular and nodular infiltrates in the lower lung fields of minimal extent and

[illegible]

of abnormal findings

[illegible]

in which you had assumed there would be only vinyl chloride exposure.

In one [illegible] case, particles of PVC were found, the scarring lesion, [illegible] lesion/on lung biopsy.

In [illegible] clinical examinations of 134 workers

exposed to vinyl chloride in a polymerization plant [illegible] [illegible] [illegible] [illegible] [illegible] abnormalities, peripheral vascular changes and lung abnormalities. The latter may reflect exposure to polyvinyl chloride dust, rather than to the monomer gas. Skin changes were not prominent in this group, although they have been well [illegible] [illegible] and [illegible] were not able to confirm [illegible] [illegible] of hypertension. Acroosteolysis was found [illegible] [illegible] [illegible] had been previously reported [illegible] [illegible] [illegible] [illegible] cases [illegible] [illegible]

[illegible], simultaneously with this clinical survey, we initiated an investigation into the mortality experience [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] industry, [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] among the polymerization workers. [illegible] [illegible] [illegible] [illegible] [illegible] [illegible] out the question that we [illegible] [illegible]--[illegible] often did [illegible].

And I thought it might be best at this point to have Dr. [illegible] give you his firsthand information of this investigation.

Dr. [illegible]: [illegible] union and company [illegible] cohort of 257 individuals was established, each of whom had been occupationally exposed to vinyl chloride for

one death. For the asbestos workers, there were 22,525 person-years at risk of 10 to 14 years and there was a single misothelioma. In 24,501 person-years at risk from 15 to 19 years, there were five misotheliomas, and from 20 to 24 years from onset of exposure, in 19,798 person-years of risk, there were nine cases.

This gives, for cases of hemangiosarcoma or misothelioma, per thousand person-years at risk, as follows: 0.9 for vinyl chloride, 0 for asbestos, in 10 to 14 years; it is 1.8 for vinyl chloride, 15 to 19 years, against 0.2 for asbestos; and 2.7 for 20 to 24 years for vinyl chloride against 0.45 for misothelioma due to asbestos exposure.

[illegible] might be useful to at least give some hint of the way the data are beginning to go.

Now, with these data as a background, we have been able to arrive at a number of recommendations which we believe will serve to sharply decrease the risk of both non-malignant and malignant toxic effects of vinyl chloride exposure.

I will limit our observations to those which are particularly pertinent to the proposed standard for vinyl chloride.

First of all, with regard to the level of exposure. Let's get right and grapple with the important problem first. The proposed standard, as you know, is for no detectable level,

using a technique which will detect vinyl chloride at con-centrations at one part per million, plus or minus 50 per-cent. I realize that this particular item, which I support, is likely to attract the greatest opposition--and if I thought so before coming down here today, it certainly has been confirmed as I sat here.

Nevertheless, the issue should be met head on, since it lies at the heart of the possibilities of success for the control of vinyl chloride cancer hazard.

Now, what do we actually know? [illegible], based upon their experimental studies, a group of excellent scientists at Dow Chemical, 15 years ago, proposed a time-weighted [illegible] upon their animal toxicity studies, this was what they proposed [illegible] for nonmalignant illness.

Dr. [illegible] reported to the New York Academy of Sciences meeting on May 11 [illegible] 1969, when the results of our toxicological studies on animals caused us to be more concerned [illegible] both vinyl and vinylidene chloride exposure, continuous monitors were installed in our polymer plants and a rather dramatic reduction in workroom air concentration was achieved. This was brought about by setting a goal that a time-weighted average exposure for an 8-hour 5-day week should not exceed 50 parts per million for vinyl chlo-ride and 25 parts per million for vinylidene chloride," and

"...in the ensuing years between 1960 and 1967 we were generally successful in reaching these goals."

Dr. Rowe further noted that, after Dr. Viola's report of tumors in rats in 1970 and 1971, a closer look was taken of Dow operations. "In our oldest monomer plant we found time weighted averages to be generally less than 2 ppm but there was one job that showed 45 ppm and another job that showed 14 ppm. Personnel monitoring during 1973 revealed that all time-weighted average values were below 10 ppm." except for some laboratory employees.

"In our second oldest monomer plant, which began operation in 1958...the highest time-weighted average exposure of [illegible] workers; all others were less than 5 ppm." "In the newest monomer plant which began operation in 1960, time-weighted average values range from less than 1 to 10.4 ppm. At the only polymer plant now operating, time-weighted average values have been markedly decreased, the levels during 1973 generally were well below 25 ppm, most of them being in the 1-5 ppm range."

Now, how can we translate Dow's recommendation of 50 parts per million for non-malignant disease to the prevention of malignant effects? The most authoritative generalization in this regard has been made by Dr. Herbert Stokinger, Chairman of the Threshold Limit Value Committee

of the American Conference of Governmental Industrial Hygienists, who has recommended that levels for the prevention of neoplasms should be approximately one five-hundredth of toxic, non-malignant levels. If we were to take Dr. Stokinger's advice, an acceptable TLV for vinyl chloride would be 0.1 part per million.

And we heard this morning from Dr. Schneiderman that two other scientists have had estimates which range from one-hundredth of the non-malignant toxic level to one-five thousandth.

So it seems that Dr. Stokinger may have made a shrewd guess and come right in the middle.

Now, in terms of human experience, we have only two benchmarks. First, the only safe level that is known is zero. At the other end of the spectrum, we know that hemangiosarcomas have occurred at levels which obtained in the past in the polymerization process. Unfortunately, we have little information concerning the details of such levels. Although there was a published TLV for vinyl chloride recommended by the ACGIH, apparently little monitoring or surveillance was done and few companies have any significant number of measurements made until recent months. Indeed, if the polyvinyl chloride-vinyl chloride companies had done their work over the last fifteen years when they should have, because there has been a TLV for vinyl chloride,

we would be able to take our 13 cases of hemangiosarcoma in the polymerization plant and with their assistance and their data work out an integrated value of exposure, and we would be able to tell you exactly what the levels were which have caused hemangiosarcoma in the past.

Unfortunately, these data are not available.

Now, we then turn to animal data, and they are of some assistance. Dr. Maltoni has a paper in press giving his results at 131 weeks of rats exposed for 52 weeks at varying concentrations (10,000, 6,000, 2,500, 500, 250 and 50 parts per million). The number of angiosarcomas of the liver, in addition to other tumors, were 9, 13, [illegible] [illegible] [illegible] carcinogenicity. He has since observed [illegible] angiosarcomas at 50 parts per million and, of course, the [illegible] Laboratories have in their preliminary results also noted that angiosarcomas have occurred in mice at 50 parts per million.

In view of these considerations, I suggest that the only prudent course for the prevention of hemangiosarcoma of the liver among vinyl chloride workers is to provide a work environment with no detectable level of vinyl chloride. Of course, accidents will occur and higher levels of VC will result; in such circumstances, as the proposed standard states, appropriate [illegible] protection should be provided.

Now, there are a number of theoretical considerations

which reinforce this recommendation. Dr. Maltoni has demonstrated important species differences in neoplastic response to vinyl chloride. Thus, mice--his original studies began with rats, but then he took mice--and the mice showed not only angiosarcoma of the liver but also lung tumors and breast tumors. Now, the mice, however, did not show kidney tumors, which the rats did.

We have no way of judging at this time what the vinyl chloride induced neoplastic spectrum would be in man. I don't know whether we are going to be more like the mice or more like the rats or more like some other animal. It may turn out that tumors other than [illegible] which [illegible] [illegible] Dr. [illegible] suggestion that [illegible] seem to be increased, may turn out to be a key observation. [illegible] incidence of [illegible] tumor among men will result in an important number of excess neoplastic deaths among vinyl chloride exposed workers.

With regard to the technical difficulties for industry, I am--I was sure before coming here that the claim was going to be made that no detectable level will cause a great deal of expense and marked hardship for industry, and I don't doubt this at all. Nevertheless, I believe that the standard is feasible and attainable. I have just quoted the levels already achieved at Dow Chemical and reported by Dr.

liver, various causes, but you don't find a palpable spleen, and in Niagara Falls we found over 2 percent with palpable spleens. This is very unusual.

But, as I said, we found it less frequently than the Germans found palpable spleens in the University of Bonn study.

MR. TOPOL: I think you made the statement during your testimony or during questions, that the only safe level is zero. By that I gather you mean that based on the current state of knowledge we can't say whether low levels are safe or unsafe, would that be a fair statement?

DR. SELIKOFF: Absolutely. The only level that we know in 1976 is zero. [illegible] turn out that 2 parts per million would [illegible] one case in 50,000 or one case in 20,000—I don't know that. The only thing I know at this moment—we are ignorant as all get-out so far.

MR. TOPOL: You mean ignorant on the question whether low levels would be safe or unsafe?

DR. SELIKOFF: That is right. The question is, what do you do in the absence of knowledge?

MR. TOPOL: You said, in that connection, that you thought that the shorter the exposure in terms of time duration, the lower the risk.

Would that be true also for the level of exposure —that is, the lower the level of exposure, the lower the

PROCEEDINGS

JUDGE MYATT: All right, This hearing is resumed.

The next witness is the representative of Prevue Products.

Proceed, sir.

MR. COHEN: Thank you. Good Morning.

My name is Zvi Cohen. I am the President of Prevue Products, Incorporated, of Manchester, New Hampshire. Prevue Products is one of the largest manufacturers of slush molded waterproff footwear in the United States.

Over the past decade slush molded footwear has become the most popular form of protective outer footwear in the United States, Especially for women and children. This process of making waterproof footwear has almost entirely replaced the conventional handmade method of making such footwear. The skills required to make waterproof footwear in the traditional fashion by the autoclave vulcanizing method have all but disappeared in this country.

There are fewer than ten manufacturers of slush molded footwear in the United States, and all authoritative estimates put the total production per year at approximately 10 million paid. In view of the fact that these boots last for a long time, it is probably true that most women and children who buy protective footwear in the snow belt of the United States are consumers of slush molded footwear.

Every pair of slush molded footwear requires PVC resin as the primary component. There is no substitute for PVC in the slush molding process, since no other material has the same manufacturing characteristics. If PVC were to become unavailable, not one pair of slush molded boots could be produced in this country.

We have [illegible] an independent laboratory conduct tests in our plant which indicate that the level of VC in our operation is less than one part per million. Of course, this is to be expected since we are working with PVC resins rather than with VC itself.

We believe that our current level of VC constitutes [illegible] any reduction below this current level. However, our suppliers have told us that if the one part per million standard were to be imposed upon them, it would be impossible for them to continue their operations. What they have told us is that something between the emergency level which was set on April the 5th, 1974, and the one part per million proposed standard could be attained in a reasonable time.

The prospect for my industry should the one part per million standard be imposed is a very bleak one. In my factory there are 500 people who would be thrown out of work should PVC resins become unavailable. Instead of the steady employer which we have been for the past nine years, we would suddenly

become no employer at all in our area. Even a reduction in our supply could gravely affect our operations, because volume is the key to our profitability.

I urgently request that the Occupational Safety and Health Administration attempt to work out a reasonable VC standard for the PVC industry which will enable our industry and many others [illegible] of the PVC resin supply [illegible].

Thank you.

[illegible]: Mr. Klein.

MR. KLEIN: I have a very few brief questions for you.

[illegible] process?

MR. COHEN: Well, it's known as the [illegible] process. It's a [illegible].

MR. KLEIN: Do you have [illegible]

MR. COHEN: Well, [illegible] the [illegible] with [illegible] to [illegible].

MR. KLEIN: Did you do your own measuring of --

MR. COHEN: No, we had an independent laboratory do the measuring.

MR. KLEIN: Over what period of time did they take those measurements?

MR. COHEN: Well, in view of the fact that we only recently realized that we had to measure for this, we did one measurement. We are now doing succeeding series of measurements to see whether the results are consistent, but this one test was done two weeks ago.

MR. KLEIN: And what were the levels that you discovered?

MR. COHEN: We [illegible] in the areas of our plant, where we think the [illegible] were most likely [illegible] and [illegible] in each of these locations we had less than one part per million. In most cases, no detectable amount.

MR. KLEIN: [illegible]

MR. COHEN: [illegible]

MR. KLEIN: Do you know what temperatures this heated to, approximately?

MR. COHEN: Approximately 150 to 500 degrees.

MR. KLEIN: Thank you very much.

JUDGE [illegible]: Are there any questions from the general audience?

Yes, Mr. Zelicsky.

MR. ZELICSKY: I'm Lou Zelicsky from the UAW.

I wasn't here at the beginning of your testimony and I heard some comments toward the end about the type of procedure that was utilized by the consultant, whoever came in to

take the air samples.

How did he collect the air samples for vinyl chloride?

MR. COHEN: I'm afraid that my chemical engineer and he did the collecting and --

MR. BELICSKY: How did you collect them, on charcoal tubes or --

MR. COHEN: I believe so.

Perhaps the gentleman who took the tests is here. He's from Grulus (phonetic) Scientific Services, and I know he's planning to attend these hearings. I'm not sure if he's present in the Hearing Room at this moment, but he could probably explain -- I guess he could give you a much more thorough explanation.

MR. BELICSKY: I guess he'll be a witness later.

In the processes that you have to make the product using the resin and the plasticol, especially at the curing ovens, do you have any ventilation in the area such as local exhaust ventilation over the curing process or curing ovens?

MR. COHEN: In every location, both mixing and curing we have very complete exhaust systems.

MR. BELICSKY: Now, this is not dilution ventilation; this is your local exhaust.

MR. COHEN: Yes.

MR. BELICSKY: Thank you.

MR. COHEN: You're welcome.

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they didn't feel that they could do one part per million.

MR. SAMUELS: Did they talk about any percentage of resin that might be produced under conditions described by the proposal?

MR. COHEN: No, they did not. Except that --

MR. SAMUELS: It was an all-or-nothing kind of judgment?

MR. COHEN: Yes.

MR. SAMUELS: Thank you.

MR. COHEN: Let me say that perhaps one of my suppliers could achieve the one part per million -- I'm not sure -- and perhaps another one couldn't. That would have the same effect [illegible] by virtue of the fact that [illegible] to locate new sources. I'd suspect that the tightening in the marketplace which would result from several producers being decommissioned would in effect result in our closing since, if we can't make but 50 percent of our normal production it wouldn't be economically feasible to run the plant.

MR. SAMUELS: In other words, you've experienced shortages of raw material before this emergency?

MR. COHEN: We have curtailed our growth because we have been unable to obtain sufficient materials, yes.

MR. SAMUELS: What do you currently pay for PVC resin?

MR. COHEN: We are now buying at the black market, if

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that's what you're -- different resins are different prices; some 32 cents per pound, others other prices.

MR. SAMUELS: Have the prices increased in the last year?

MR. COHEN: Yes, they have. Since -- yes, they have all increased in the past year.

MR. SAMUELS: Have you heard [illegible] of the industry's plans to increase the number of plants producing PVC resin in this country?

MR. COHEN: [illegible] plants [illegible] realized. I don't know exactly how many --

MR. SAMUELS: Thank you.

MR. COHEN: [illegible] I have approached the producers with whom I have no present relationship whom I know to be building new plants, they've told me that there is no production available from the new plants -- even though the plants won't go on line for 18 to 24 months, because they're all sold up already.

So I consider the situation rather bleak from our position if one of the producers we're currently doing business with should be forced to close down.

MR. SAMUELS: Well, have you asked or has it been suggested that you testify by any of your suppliers?

MR. COHEN: I think that every supplier who wants to tell me about the present situation suggested that it might be

21 these materials, develop an acute reaction referred to as metal fume fever. Other particulates may be carcinogenic.

Gaseous -- molecularly dispersed -- hazards may or may not be immediately life-threatening. Examples of gaseous toxicants are carbon dioxide, carbon monoxide, ozone, oxides of nitrogen, phosgene, and phosphine.

The selection of respiratory equipment depends upon the classification of and the type of hazards for which it is to be employed. Among the factors to be considered are whether the hazards are immediately dangerous, what the concentration of the contaminant is, the particle size of the contaminant, whether the respiratory equipment is going to be used as emergency equipment or whether it is to be used on a day-to-day basis, and the duration of usage, whether it is one hour or eight hours per day.

Basically, there are three types of respirators: One, the air purifying mechanical filter or chemical canister adsorption gas mask type; the second, the air-supplied air line hose mask, with or without blower; and, third, the self-contained breathing equipment which operates predominantly in a non-rebreathing manner utilizing valves, compressors or cylinder air sources.

The air purifying type, Class 1, are used to remove contaminants from an atmosphere that contains an adequate amount of oxygen. They work by either filtration or adsorption

or by chemical reaction to remove the contaminant. Although not of direct concern in the present context, it should be noted that respirators intended to filter particulates offer no protection against gases or vapors.

Air purifying respirators produce high resistance to breathing. Adequate fit to the face contour because of differences in size and shape and anthropological characteristics is often a problem, and many times masks must be molded to the individual characteristics. As a result, leakage can commonly occur [illegible] are taken.

As mentioned, resistance to breathing exists, [illegible] more severe demand on the respiratory system and decrease the efficiency of an individual's performance. To prevent the clogging of the canister and to decrease the resistance to breathing, it is permissible to remove the filter within such units where protection against particulates is not required.

The resistance is provided [illegible] on inspiration and on expiration, thus increasing appreciably the work of breathing. As a result of the above inadequacies, most workers discard filter-type masks, refuse to wear them, especially if they can't see the dust. Yet this fine, nonvisible dust may be the most harmful.

The chemical cartridge types are half face masks and

have exhalation valves. The cartridge is filled with chemicals such as activated charcoal, soda lime or silica gel for the elimination of the contaminant. They have very limited application and are of value when used against vapors and gases of low toxicity.

Canister-type gas masks have attached to them a canister containing [illegible]. Such masks are of value in protection against [illegible], acids, ammonia, carbon dioxide. They [illegible] provide effective and reliable protection. The protection depends upon the canister and upon its contents. The gas masks offer appreciable resistance to breathing, however.

The second group of respirators mentioned was the air-supplied respirators, a type [illegible] attached to an uncontaminated air source. These may be equipped with or without blowers. They may have an air line attachment of continuous flow or for use in demand-type of respirators. They may be used with a full face mask, with hoods, or with full body suits They are usually designed for specific tasks or for hazardous environments not otherwise controllable. They are relatively simple in design, but need a good air supply.

When blowers are employed with such respirators, it is necessary to have an individual attending the blower as a standby. An example of the valuable application of the hose air-supply respirators is in the occupation of sandblasting.

However, I recently -- at the present time I have a patient in the hospital who had ten years exposure to sand-blasting who has severe third-stage conglomerate silicosis and in taking his history I found that there were many occasions that he admitted to the fact that he did not wear his respirator because of some of the difficulties encountered in its use.

Such respirators produce increased resistance to breathing. They frequently have a long hose attached to them, which in itself may be a nuisance or a safety hazard. There are limitations on the maximum length of hose that can be used the with air-supplied respirators. If the respirator is one that is going to be used without a blower, then the tube coming from the air supply should be less than 50 feet in length. If it is to be used with blowers, the tube length may be anywhere from 150 to 250 feet. Such types of respirators are used when one wishes to enter a closed environment, such as tanks, tunnels, pits or where dust vapors and gases may be present.

The air line leading to the facepiece may be attached to a compressed air source, either a compressor or a gas cylinder. The cylinders are under high pressure; therefore, pressure regulators, relief valves, and the demand-type of regulators are needed.

Many of the air-supplied respirators employ a slight positive pressure in order to prevent inward leaks at the face. They are good for hazardous environments not immediately

25 dangerous to life. Examples: spray painting and welding. They can be used continuously, but one must be sure that the air which is being provided is free of carbon monoxide and carbon dioxide.

For example, I had a situation not too long ago where I had a tank of compressed air delivered to me prior to using it for human breathing purposes. As is our policy, we analyzed the gas prior to using it. I analyzed the air and found that it contained 3[illegible] percent carbon dioxide. In tracing the source of the supply of air, it was found that the compressor was drawing air from an area above an incinerator that was in operation.

[illegible] these are some of the realities that are encountered when one has to deal with breathing equipment and breathing devices.

Other factors besides the hose size and hose weight to be considered with air-supplied masks are temperature and humidity. If air is breathed from a cylinder containing a dry gas, this can dehumidify the respiratory system and extract moisture from the system and be a source for irritation and for exposure to infection and produce discomfort in the individual.

The last group of respirators is the self-contained type. These provide complete respiratory protection for any concentration of toxic gas or oxygen deficiency. They can be used with an air source or an oxygen source. They are usually

employed in emergency situations. The self-contained apparatus is heavy, bulky, requires highly trained individuals for its use. It can be of a demand or of a rebreathing type.

In the pressure demand type, the slight negative pressure initiated by the individual at the beginning of inspiration triggers the valve so that the gas will flow as it is needed at an appropriate flow rate. Such pressure demand systems must be flow sensitive as well as pressure sensitive and allow the individual to breathe in gas at whatever maximum flow he desires. In performing a normal flow volume curve on a patient we find that that flow, maximum peak flow will run in the neighborhood of 35 liters per minute. During exercise, during activity [illegible] breath [illegible] flow can be in the neighborhood of 400, 500 or 600 liters per minute.

If the supply unit is supplying gas at only 35 or 40 liters per minute, it will be necessary for that individual to supplement his air from some other source, usually an emergency relief valve.

These systems are non-rebreathing systems and, therefore, discharge the air away from the mask or from the individual. It is necessary when one employs self-contained respirators to have warning devices indicating that the pressure supply is getting low.

Well, so much for the types of equipment.

Let us now look briefly at some of the other problems

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associated with respirator use.

The first that comes to mind that of safety, the fit and improper sealing of the mask. If a leak occurs at the mask -- especially an inward leak -- the toxic materials may be inhaled and a false security be provided. As mentioned previously, there is marked variability in the contour of faces. It is very important that any mask fit comfortably. Otherwise, an individual using it over a long period of time may find a mask to be intolerable.

When effort is expended and work is performed requiring increased oxygen demand, perspiration is not adequately evaporated; it remains within the mask producing an unpleasant effect. Toxic substances may become trapped between the skin and the face causing local irritation or absorption. I am reminded of a situation in the United States Air Force where we were asked to investigate a series of reactions occurring to pilots in a particular type of plane. These reactions were thought to be due to carbon monoxide. However, it turned out that the irritation, unpleasant odor, and gastric reaction they were experiencing was due to mercaptans found within the tubing. Related to this is the observation that allergic or sensitivity reactions to materials have been known to occur.

Psychological problems associated with the use of respirators have been observed. Many people find the confinement and sense of isolation distressing; others are uneasy

about the need to work in an environment that requires the use of such equipment.

Another problem associated with the use of respirators and masks is dead space. It is very important that the individual not rebreathe exhaled air and that the dead space in the mask be kept at less than 150 cc or that the mask be adequately ventilated to flush out the dead space. Otherwise, there would be rebreathing of exhaled carbon dioxide and a deficiency in inspired oxygen.

The eyepieces on the full-face masks is of importance. These must be leakproof. They should not distort the vision. They do decrease the field of vision. In an individual wearing glasses, the glasses can be protected or the mask eyepiece itself may become fogged. The individual with bifocal vision may have difficulty looking through the eyepiece and performing his tasks. It may be necessary to construct the eyepieces by means of special grinding with built-in corrective lenses for an individual. Antifogging compounds may have to be employed to prevent fogging, or it may be necessary to wear a nose clip to prevent fogging of the eyepieces or the glasses. All of these can decrease efficiency and be uncomfortable and unpleasant to the individual, which, in turn, makes the wearing of the mask a difficult task.

Another problem associated with masks is speech transmission. Upon movement of the jaws, the mask may become

distorted and leaks occur. It may be necessary to equip the masks with special diaphragms, microphones, amplifiers, and radios in order to provide ability to communicate.

A very important consideration in the wear of respirators pertains to persons who are found to be suffering from bronchitis, emphysema, and chronic asthma. Such people should not be employed in work entailing the use of a respirator. This limitation knocks out a large segment of our working population.

Surveys have demonstrated that the incidence of chronic obstructive pulmonary disease in males over the age of 35 runs approximately 22 percent. Dr. Selikoff yesterday gave us a figure in the vinyl industry in some of the older men -- or the older men [illegible] the [illegible] in the range of 58 percent. That is significantly above what we found in our surveys.

And there appears to be -- in our surveys there was very little difference in the incidence of chronic obstructive lung disease in females. It ran around 25 to 28 percent.

If one looks at the entire population, including children, and the entire spectrum of age, the incidence of chronic obstructive lung disease may run as high as 3 percent. Patients with chronic obstructive lung disease would find the resistance and the other factors associated with the wearing of the masks to be unpleasant and cause further difficulty in their

breathing. In the first place, they shouldn't be in an environment that is contaminated and, secondly, they should not be asked to wear respirators.

Respirator training programs are needed where the individual who is to wear the mask can be properly instructed in its use, its workings, and its care. Respirator maintenance programs must be developed where masks are used. These masks should be inspected monthly. They have to be cleaned and examined after each use. If they are going to be used by more than one individual, they have to be cleaned and cared for daily. They must be washed in soap and water or with detergent and allowed to air dry or be dried by forced air, occasionally [illegible] contaminated or it may become a source of bacterial contamination and disease transmission. Cleaning and repair stations have to be set up where masks or respirators are being used.

Storage is another factor that must be considered. Proper facilities must be provided to keep the respirators and their component parts in good condition.

In summary, prevention is the main defense in occupations that pose respirator hazards. It is best to eliminate contaminants at the source or to decrease the concentration of the contaminants to an acceptable, allowable, safe limit. Where such cannot be accomplished, protective equipment should be considered.

Thank you.

JUDGE MYATT: All right, Doctor.

Mr. Klein.

MR. KLEIN: Doctor, have you worked with vinyl chloride and respirators?

DR. TOMASHEFSKI: No, I have not.

MR. KLEIN: Do you know whether the vinyl chloride gas combines with particles and can be inhaled in that manner?

DR. TOMASHEFSKI: I would assume, such as many other gases can adhere to particles and it would be inhaled, on the basis of just general principles and physical chemical properties.

MR. KLEIN: Do you know whether vinyl chloride is absorbed through the skin?

DR. TOMASHEFSKI: From my reading I have been informed that it can be absorbed through the skin.

MR. KLEIN: I take it you were present during Dr. Myatt's -- Mr. Myatt's testimony yesterday; is that correct, sir?

DR. TOMASHEFSKI: Yes, I was.

MR. KLEIN: Are you in disagreement with his recommendations?

DR. TOMASHEFSKI: Not really. I think we are in line. We're both showing some of the limitations to the use of respirators. We both feel that if there is some other means by

33 which this can be accomplished, that it is preferable. [illegible] however, it cannot be accomplished, then a respirator can be used.

The type of respirator depends upon the situation. I mentioned here in my conclusion that a canister-type can be used safely for short periods of time when the concentration is not excessive.

I think he mentioned that in certain circumstances it might be necessary to wear an air line or a air hose-supplied type of a mask.

MR. KLEIN: Are you aware of any specific canisters that are on the market today that would be effective as a respirator for [illegible]

DR. TOMASHEFSKI: No, I am not. However, I've been informed that such are in the process of being developed and perhaps there are others who might know that there is such in existence, but I do not know of any.

MR. KLEIN: Dr. Lassiter would like to ask a few questions.

DR. LASSITER: Just as a point of departure with your Air Force experience, isn't it normal in the Air Force that some crews will wear respiratory protective devices for, say, extended periods of greater than four to eight hours during operations?

DR. TOMASHEFSKI: Yes, this is quite true. Many times

34 a man is on oxygen continuously during high performance-type aircraft in high altitude flights.

DR. LASSITER: Do you consider that most of the problems inherent with the type of respiratory protective devices that you mentioned today are primarily because these types of devices are designed for short-term effects such as you mentioned and that you consider it might be feasible that aside from the individual respiratory problems that you mentioned with some diseased individuals, then a respirator protective device designed for a longer time period, say, four to eight hours, could be designed or could be developed?

DR. TOMASHEFSKI: In part that is true. But I think [illegible] Force personnel wearing a mask for a period for six or eight hours. They're breathing it for a primary purpose and that purpose is for adequate oxygen delivery. They are not breathing it for the removal of particulates or removal of contaminants within the atmosphere, so it's for an entirely different purpose.

Where we talk about contaminants and other pollutants then these factors that I mentioned come into consideration.

DR. LASSITER: Getting back -- I just mention this as a design to show that some individuals do do this, not saying that perhaps the industrial situation will be apropos for the same type of respiratory protective device. What I wanted

to have you address yourself to as an expert in the field is whether you feel that presently designed devices are designed for short-term wear, and do you think that it's even feasible that aside from trying to protect individuals that have diseased respiratory tracts, for a normal worker is it possible that a respiratory protective device could be designed? Is it feasible this could be accomplished?

DR. [illegible]: [illegible], I think it's feasible, yes.

DR. [illegible]: Thank you.

MR. [illegible]: We have nothing further at this time, Your Honor.

JUDGE [illegible]: Mr. [illegible].

MR. [illegible]: Thank you, Dr. [illegible].

[illegible] your responsibility there, specifically you act as a chest physician?

DR. [illegible]: That is correct.

MR. [illegible]: Have you had any experience at the Cleveland Clinic in any chance of worker exposure to vinyl chloride?

DR. [illegible]: No, we have not. However, I do have experience with other types of occupational diseases.

MR. [illegible]: I'm aware of that.

Have you ever visited a plant that manufactures either vinyl chloride or a polyvinyl chloride resin?

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DR. TOMASHEFSKI: The closest I came to that was a pilot plant that was set up at Battelle Research Institute.

MR. BELICSKY: That may have been a few years ago.

DR. TOMASHEFSKI: That was a few years ago, and that was specifically for research purposes.

MR. BELICSKY: Before we had an awareness that vinyl chloride could produce [illegible] of the liver?

DR. TOMASHEFSKI: That is correct.

MR. BELICSKY: Have you worn a respirator in any particular operation related to industrial exposure?

DR. TOMASHEFSKI: Yes, I have.

MR. BELICSKY: For how many hours?

DR. TOMASHEFSKI: [illegible] respirators in the Air Force for periods up to six and eight hours. I've been a subject in environmental experiments where I've had to wear respirators for periods of -- for long times.

But most of them have been for the delivery of a gas such as oxygen, rather than removal of a particulate.

MR. BELICSKY: Have the use of the respirators in any way affected you physically?

DR. TOMASHEFSKI: I can recall one instance where the exhalation valve stuck on me and, fortunately, I had someone else in the chamber with me, or I might not be here to tell my story. I felt considerable resistance --

MR. BELICSKY: The point I'm making --

DR. TOMASHEFSKY: -- I had to take the mask off and replace it with a new one.

MR. BELOSKY: Excuse me. That was an accidental occurrence.

DR. TOMASHEFSKY: It was a nonfunctioning valve. There was resistance in exhalation.

MR. [illegible]: [illegible] from the ordinary operation and use of a respirator that provided oxygen to you or whatever you used in a pulmonary function test or whatever way the respirator was worn, it probably didn't affect you physically or such?

DR. TOMASHEFSKY: No, it did not -- except to say that it did cause restriction -- there is resistance to breathing and [illegible].

MR. [illegible]: All right. Can you discuss the merits or demerits of a demand-type [illegible] supply [illegible] continuous flow supply equipment?

DR. TOMASHEFSKY: The demand-type delivers the gas at the individual's demand in a volume that is required at a flow rate that is required. This is [illegible] a valve, a [illegible] valve or a pressure demand valve attached to a compressed air source or some other source.

The air line here or the hood-type mask can have a blower attached to it and blow the air through the system so there's a continuous flow of air through it or it just may be out into a fresh air supply where the individual has to draw it

on his own accord through the system.

MR. BELICSKY: Have you seen continuous flow supply respirators used in any industrial environment?

DR. TOWNSHENDKY: At Battelle we had occasion -- we had several occasions where we required --

MR. BELICSKY: In the pilot plant operation, but not [illegible] --

DR. [illegible]: [illegible] this wasn't only -- we had many other [illegible] required, [illegible]

MR. BELICSKY: [illegible] supply air hoods, where continuous air flow is provided. Do you [illegible]

DR. [illegible]: [illegible] a hood, no.

MR. BELICSKY: [illegible] statement about the fact that you had read in the literature or had seen documented information regarding [illegible] of vinyl chloride. Could you provide [illegible] --

DR. [illegible] regulations. I think it came out of the Department of Health -- Department of Labor regulations --

MR. BELICSKY: I thought --

DR. TOWNSHENDKY: -- that skin absorption can occur.

MR. BELICSKY: I thought this was some technical journal to which you referred.

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DR. TOMASHEFSKI: No. There's not much in the technical and the medical literature on vinyl chloride.

MR. ZELKOSKY: One more question. Do you think there is a substitute for respirators?

DR. TOMASHEFSKI: Only good hygiene principles and removal of the contaminant.

MR. [illegible]: If [illegible] and such that the only way an operation can feasibly be conducted without injuring an individual, would you [illegible] your respirators?

DR. [illegible]: [illegible] only [illegible] I would require that they [illegible].

MR. ZELKOSKY: Thank you.

[illegible] questions?

Mr. Samuels.

MR. SAMUELS: Doctor, have you ever conducted a respirator program in a plant with real workers? That is to say, a program of [illegible] workers on their use, their use and cleaning?

DR. TOMASHEFSKI: [illegible] research institute.

MR. SAMUELS: But not in a plant?

DR. TOMASHEFSKI: Not in an actual industrial plant.

MR. SAMUELS: Have you ever recommended to any of the employers for whom you consult that perhaps prolonged breaks in clean areas for workers who must wear respirators would assist them with any pulmonary deficiency that they might have?

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MR. NICHOLSON: My name is Nicholson. I'm from Mt. Sinai School of Medicine.

I just have a couple of brief questions and they bear upon the different -- the relative effectiveness of supplied-air hoods versus the canister-type masks.

Could you comment specifically on the relative breathing resistance of these two devices under normal operations?

DR. TOMASHEFSKY: I'm sorry, I cannot. Recently, however, there was a very fine article in "The Journal of Environmental Health," and I think by Hartley, et al., where they studied the resistance of canister-type and filter-type respirators and found that to be -- to be a very significant [illegible] a comparison in there on different types of respirators, so I would recommend that particular article to you.

MR. NICHOLSON: I understand, as you stated, that the filter-type, the canister-type respirators do have a relatively high resistance to breathing. Isn't that the case, that in most supplied air hoods the resistance to breathing is relatively low?

DR. TOMASHEFSKY: In supplied air hoods, that's very true, especially with a continuous flow.

MR. NICHOLSON: Yes.

DR. TOMASHEFSKY: Or with the blower type it could be quite low.

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MR. NICHOLSON: That was the specific difference I was wanting to raise, that as far as that factor goes, the comfort of a supplied air hood would be greater.

DR. TOMASHEFSKI: They can be quite comfortable, yes, because they're cool and there's very little resistance.

MR. NICHOLSON: Furthermore, would not this resistance of the canister-type be enhanced, that is, the resistance is increased, by the concomitant presence of particulate matters, a very high concentration of particulate matter --

DR. TOMASHEFSKI: Considerably increased, because the filter that you'd apply on there would add additional resistance.

MR. NICHOLSON: That's right.

In view of the possibility of both particles and gases being present over a long period of time, would you still continue to recommend the canister-type as --

DR. TOMASHEFSKI: Than this --

MR. NICHOLSON: -- the only respiratory protection device?

DR. TOMASHEFSKI: When this problem was presented to me, I addressed myself to the gas and the recommendation here pertains to the gas.

Now, if a particulate is added, then I think one should modify that to include the particulate.

MR. NICHOLSON: Okay. One final question and that

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JUDGE HYATT: Proceed, gentlemen.

MR. KLEIN: Excuse me, Your Honor. I would request that you ask the witnesses for an extra copy for us.

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THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

RALPH L. HARDING, JR.

MR. HARDING: Judge Hyatt, my name is Ralph L. Harding, Jr. I am president and chief staff officer of the Society of the Plastics Industry, Incorporated, SPI.

After a few brief remarks to complete the record regarding SPI, I will be introducing the witnesses who are appearing today on behalf of the vinyl chloride and polyvinyl chloride producers' committee, an operating unit of SPI.

SPI is the industry association for the plastics industry. Our 1,400 members and 50 operating units include producers of the plastics raw materials or resins and of the various modifiers and adjuvants used, the plastics machinery and mold builders, and, of course, the processors or converters of the resins into finished components or products. We estimate that our membership represents over 95 percent of the plastics materials and machinery produced in the United States and about 75 percent of the processing volume.

In 1973 total plastics production was 27 billion pounds. The four principal plastics were: polyethylene, 9.4 billion pounds; polyvinyl chloride and other vinyls, 5.4 billion

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pounds; polystyrene and its co-polymers, 5.0 billion pounds; and polypropylene, 2.2 billion pounds.

As you know, polyvinyl chloride is a solid material produced by several polymerization processes from vinyl chloride monomer, which is a gas. In the United States there are 13 vinyl chloride monomer producing plants and [illegible] plants in operation which polymerize the monomer into polyvinyl chloride. Twenty-two companies representing over 99 percent of VCM and PVC capacity are active members of SPI's VCM and PVC producers' committee.

At least 600 of SPI's processor members are active in converting PVC into component or end products. Our Society's concern with PVC thus begins with the manufacture of VCM and carries forward through the polymerization into PVC, the various conversion processes such as calendering, blow molding, extrusion, injection molding, and other processing and finishing operations, to its utilization of end uses, and ultimately to its disposal or recycling. In a few minutes one of our witnesses will be describing the economic and employment involvement of PVC in considerable detail.

SPI was officially requested to become involved with the VCM and PVC producers group on April 15, 1974. Prior to that date our own staff and general counsel had been involved tangentially with VCM problems pertaining to the Food and Drug Administration. This was because the logical concern of the

65 be from Mr. Vittone.

MR. HARDING: Judge Myatt, our next speaker is Anton Vittone, Chairman of the SPI Vinyl Chloride and Polyvinyl Chloride Resin Producers' Committee, and he's also President of the B. F. Goodrich Chemical Company.

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THE SOCIETY OF THE PLASTICS INDUSTRY, INC. AND B. F. GOODRICH CHEMICAL COMPANY

ANTON VITTONE

MR. VITTONE: My name is Anton Vittone. I am President of B. F. Goodrich Chemical Company, a division of the B. F. Goodrich Company. Our headquarters are at 6100 Oak Tree Boulevard, Cleveland, Ohio.

I graduated in Chemical Engineering with a Master's Degree in 1939 from the University of Washington at Seattle. For the past 32 years I have been employed by the B. F. Goodrich Company. Most of my experience with Goodrich has been in the fields of manufacturing, development, and engineering, having started as a shift foreman in manufacturing.

Since April 16th, 1974, I have served as Chairman of the Society of the Plastics Industry's Committee of Vinyl Chloride Monomer and Polyvinyl Chloride Producers. Members of this committee represent over 90 percent of the current United States capacity for the production of vinyl chloride and polyvinyl chloride resins.

I have prepared a statement in behalf of SPI and the

in industries that produce or depend on PVC for the manufacture of countless products.

The production of vinyl chloride, its polymerization into PVC resin, and the processing of PVC resin into semi-finished or finished products is treated in the proposed permanent standard as one industrial health problem. However, each is an entirely different manufacturing operation posing its own problems, permitting and requiring different solutions. Of the hundreds of thousands of workers whose jobs are dependent on PVC, only 6,500 are involved in the manufacture of vinyl chloride and polyvinyl chloride resins.

Furthermore, that segment that involves the production of polyvinyl chloride is not monolithic in operation. Several different processes are utilized with many process variations and with a wide variety of polyvinyl chloride resin products. Current installations are extremely varied and do not lend themselves to the simple solution of a restricted area where employees would only work for a brief part of the workday and, thus, be able to utilize self-contained breathing apparatus as provided for in the proposed permanent standard.

The imposition of the "no detectable level" as provided for in the proposed permanent standard would require the full-time utilization of self-contained breathing apparatus during the work period in vinyl chloride and in PVC resin producing facilities. This would impse a severe and

unnecessary physical burden on our workers as well as a potential health and safety problem. Further, because of space limitations, it is impossible to use self-contained breathing apparatus in cleaning reactors.

Historically, the greatest exposure of workers to vinyl chloride has occurred in the polyvinyl chloride production segment of the industry.

Currently the level of exposu[illegible] lower in the vinyl chloride production segment of [illegible]ustry. Nevertheless, the imposition of a "no detectable level" standard for this segment of the industry as proposed would, as in the case of the PVC resin plants, require the full-time utilization of self-contained breathing apparatus with the problems and potential hazards I have already mentioned.

The third segment of the industry is that of processing and fabrication where the level of exposure is the lowest. Available data indicate that worker exposure in most work areas is at "no detectable" levels as defined by the proposed standard.

The areas of potential exposure are those involving bulk unloading, storage, and mixing areas. Even in these areas it appears that level of worker exposure can be reduced to low levels by known engineering solutions. In addition, the reduction of residual vinyl chloride monomer in the PVC resin by the PVC resin producer will further lower the potential of

losses from this source, has made progress and should continue to make progress. Nevertheless, this one type of loss will, in today's plants, provide detectable levels of vinyl chloride in many work areas. This is the primary source of vinyl chloride in the work atmosphere of today's polyvinyl chloride and vinyl chloride plants.

The identifiable losses are those losses which take place from our processes which are inherent in today's plants. While we know of their existence, they are not precisely measured but can be estimated. Technological improvements requiring time for research and development, followed by procurement of equipment and installation, can reduce these losses. Any timetable projecting lower levels of exposure is dependent on projection of technological achievement.

The industry has made progress in reducing its losses of vinyl chloride as well as polymer from its processes. I am aware of newer PVC resin plants which have reduced total losses of PVC resin and vinyl chloride to 2 percent. This compares to an approximate 5 percent for the industry in total.

The industry recommends the following standards for polyvinyl chloride resin plants as representing the maximum reduction which a majority of the industry believes feasible:

Effective October 5, 1974, a ceiling of 40 parts per million of vinyl chloride and a maximum daily time-weighted average of 25 parts per million. Levels above 40 parts per

million would require the use of practical and effective respiratory protection.

Effective October 5, 1975, a ceiling level of 25 parts per million with no time-weighted average. Levels above 25 parts per million would require the use of practical and effective respiratory protection.

Effective October 5, 1976, a ceiling level of 25 parts per million with a maximum time-weighted average of 10 parts per million. Levels above 25 parts per million would require the use of practical and effective respiratory protection.

That sequential monitoring be required of work areas with proper alarms to limit exposures to those recommended. The peak exposure levels would be determined by the sequential monitoring system with a built-in 10-minute average sample and/or by a 10-minute grab sample. Instantaneous readings for determining exposure levels are highly unreliable.

The location and number of sampling points would be determined by statistical methods to make certain that the measurements represent the work areas."

The state of the technology today is one where excursions of vinyl chloride in the work atmosphere for one reason or another do occur, although the average level of vinyl chloride in the work atmosphere throughout the day is considerably below the level of such excursions.

The imposition of the 10 parts per million ceiling would require the utilization of respiratory equipment for those periods of time when such excursions occur and when corrective action is taken.

The utilization of respiratory equipment for this purpose would not be excessive and, therefore, feasible. The adoption of a 25 parts per million time-weighted average exposure as of October 5, 1974, would in practice result in substantially lower time-weighted average exposure for the working population than indicated by the 25 parts per million time-weighted average since this is a time-weighted ceiling.

The adoption of a 25 parts per million ceiling as of October 5, 1975, would require industry to make substantial progress in reducing levels of exposure during the one-year period. A 25 parts per million ceiling will further substantially reduce the time-weighted average exposure. Theoretically, it could allow for an occasional 25 parts per million time-weighted average. However, exposure in such event is highly unlikely and would be rare.

The further imposition of a 10 parts per million time-weighted average standard on October 5, 1976, would, again provide assurance of lower levels of exposure for, again, the 10 parts per million time-weighted average would become a ceiling by this method of measurement and, in practice, would result in substantially lower time-weighted average exposure

for the working population.

The industry believes it is feasible to operate under more restrictive standards in its vinyl chloride monomer producing operations.

The industry recommends the following standard for levels of exposure in its vinyl chloride monomer producing plants as representing the maximum reduction which a majority of the industry believes feasible:

Effective October 5, 1974, a ceiling of 25 parts per million and a maximum time-weighted average of 10 parts per million. Levels above 25 parts per million would require the utilization of practical and effective respiratory protection.

Effective October 5, 1977, a ceiling of 10 parts per million and a maximum time-weighted average of 5 parts per million. Levels above 10 parts per million would require the utilization of practical and effective respiratory protection.

As in the case of the polyvinyl chloride resin plants, the adoption of a time-weighted average standard would result in a practical exposure below these ceiling time-weighted average values.

It should be recognized that these proposals represent ambitious, difficult levels of operational exposure dependent on large expenditures of money, reduced capacity, and the development of technology not currently in hand. Many companies will probably require variances of time or methods;

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The time-weighted average exposure can be very low in comparison to some of the readings sometimes.

There are, of course, certain operations where if you did not protect your employee with respiratory equipment, he would get much higher exposure. I'm talking about the cleaning of the reactor vessels, for instance. Today in our company we use respiratory equipment.

The reason I'm concerned about that is that if you loosen the polymer on the walls, you can get more vinyl chloride at times into the work atmosphere, so we take the adequate additional protection by using respiratory equipment during that period of time.

MR. KLEIN: What kind of respirator equipment do you use?

MR. VITTONE: We're using air-fed.

MR. KLEIN: I'm sorry?

MR. VITTONE: Air-fed respiratory equipment, hose, for this purpose.

MR. KLEIN: I understand that B. F. Goodrich is going to testify; is that --

MR. VITTONE: Yes, they are.

MR. KLEIN: Okay. Perhaps we can -- I guess it would be better to leave that until the specific areas.

You don't have any industry data with respect to job classification exposures?

103 parts per million, why did you include that?

MR. VITTONE: Again, the same type of thing; to provide greater protection for the worker.

MR. KLEIN: I'm a little bit confused. Perhaps you can help me with this. In PVC resins you allow employees to be exposed without respiratory protection at, say, 25 parts per million, but in the VC operations you would require a respirator, and I'm at a loss as to why.

MR. VITTONE: This is based on feasibility, and on feasibility you could do it in the VCM operations. The requirement would be rather limited, again, that they'd have to wear a respirator.

MR. KLEIN: I understand you have somebody on respirators?

MR. VITTONE: Yes.

MR. KLEIN: Okay. I won't ask you anything on that, then.

At page 14, I believe, you talk about the level of unreacted monomer. How did you arrive at the 100 parts per million figure? Why do you think it's technically feasible to get to that level?

MR. VITTONE: We arrived at the hundred by dividing by ten, as you can see, trying to set another level.

As to the technical feasibility, I think everyone in the industry is working on methods for removing the vinyl

104 chloride from the polymer. Now, we're not saying that we're going to have it -- we're not saying that we're going to have all resin at that level by 1977, but we're saying that we think we can have the majority of it.

Now, as to technical feasibility, there are different approaches. One approach, of course, is trying to strip it out, as was mentioned yesterday -- strip it out by steam, and we have, of course, in my own company a pilot plant operation going for a certain resin in this area.

Not all resins are the same -- but, anyway, that is one approach.

Another approach is to try to react the remaining monomer with something else to convert it. It's the scavenger approach.

A third that might be considered and one probably highly unlikely to achieve technologically is to find a method to react that remaining vinyl chloride to make PVC out of it, but this we find rather technically -- it seems pretty far out.

Now, I should point out to you that not all resins are the same; that we've got certain resins that are much higher in monomer than others, and some of these resins we do not have clues [illegible] you as to how to reduce them, necessarily, to this particular level.

The reason for the time frame, of course, is to complete what R and D we are doing today and the purchase and

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installation of equipment to get there.

MR. KLEIN: Is it likely that the reduction in the unreacted monomer could have an effect on the quality of the resin which is produced? Is that a problem?

MR. VITTONE: That is a problem, and that's just one of the things that we're working on in the R and D end as part of the technological study.

I'm sure anyone familiar with PVC realizes that it does degrade under high temperature and, therefore, you may have a problem if you're stripping under very high temperature.

MR. KLEIN: With respect to your plant, do you know how many parts per million there are unreacted in the resin?

MR. VITTONE: Yes. I can give you a feel for it. It's quite variable. In the plastisol-type -- I expected that question, so I jotted down a few notes, if I may -- in the plastisol or this Persian type of resin -- this is the type of resin that the gentleman was talking about yesterday about making belting -- an average figure would be around 25 parts per million. Now, that's an average figure. You have some above that and some below.

In the rigid -- well, let me see -- in high porosity extrusion resins, around 25 parts per million; co-polymers, in our case -- and by "co-polymers in our case," there's polymers and vinyl chloride and vinyl acetate and vinyl chloride, vaniladine (phonetic) chloride, we're well over a thousand.

MR. CLARK: Is it true, Mr. Vittone, that your group does concede at least a substantial likelihood that vinyl chloride is a causative agent in producing angiosarcoma? At least that you have operated under that assumption?

MR. VITTONE: We have operated on this basis: vinyl chloride has been shown to cause angiosarcoma in animals. The deaths that have been reported in PVC producing plants had the thread of vinyl chloride, and therefore we connect the two.

MR. CLARK: And you don't take exception to the animal studies -- at this time -- which have been conducted which do show occurrences of angiosarcoma at as low as 50 PPM's over the duration indicated in those tests?

MR. VITTONE: We take no special exception to that data. As I said in my earlier testimony, we are well aware of it.

MR. CLARK: Now, I take it that you have also conceded that you do not know what levels, if any, of exposure to human beings is a safe level?

MR. VITTONE: We will be presenting additional information later on in this session, and I prefer that that question be asked later after that testimony.

MR. CLARK: You will be proposing --

MR. VITTONE: There is some later testimony on this subject.

on a day-to-day basis or during your seven hour exposure period. Say if your exposure was at 50 ppm, what was the fluctuation, plus or minus, approximately?

DOCTOR KEPLINGER: Well, again, I don't have the actual figures with me. By and large, if it's 50, it might perhaps vary from something like 45 to 55 as an extreme.

QUESTION: Plus or minus ten percent more or less, then, you are saying?

DOCTOR KEPLINGER: Right.

QUESTION: On the basis of your findings, realizing they are preliminary to date, how would you characterize the carciogenic potential of vinyl chloride for the animals you have exposed?

DOCTOR KEPLINGER: Well, the main thing you can indicate is with mice and based on these results it does appear to be carciogenic in the mouse.

QUESTION: What about the hampster and rat, the ones that are confirmed?

DOCTOR KEPLINGER: Well, I think that in order to make a strong yes or no statement, one would need more information. You would have to agree, perhaps, the indication is there.

QUESTION: Well, would you be able to say at this point on these other two species that it appears likely that vinyl chloride was responsible for the induction of the observed angiosarcomas in these animals?

The [illegible] materials could be substituted for [illegible] less than one [illegible] and therefore, would have a [illegible] upon [illegible] the potential job and domestic [illegible]

[illegible]

[illegible] of our [illegible]

[illegible]

[illegible] among the [illegible]

[illegible]

[illegible] in 195[illegible]

[illegible] in the U. S.

[illegible] material which is [illegible] under standard conditions [illegible] liquid then transported and [illegible]

[illegible] as such, cannot be processed but must be [illegible] such as plasticizer, stabilizer and coloring [illegible] basic [illegible] in order to fabricate [illegible]

ms-19 local areas.

Thank you.

JUDGE MYATT: All right.

Mr. Kline?

(3) MR. KLINE: Mr. Piccaglia, did you study the question of whether or not the proposed standards would actually shut down the industry immediately?

MR. PICCAGLIA: Sir, our contract with EPA was not at all directed to that question.

We did not assess that at all in this study.

We were asked -- I am sorry. I will end my comment there.

MR. KLINE: Please go ahead if you have something to say.

MR. PICCAGLIA: I believe my statement here, I outlined specifically what our task was.

MR. KLINE: So, then, I assume that you have no idea as to whether or not the industry would be shut down by the proposed standards?

MR. PICCAGLIA: Not at all, sir.

MR. KLINE: When you take this type of study, will you tell us what types of sources you used for the underlying facts and material?

MR. PICCAGLIA: Certainly.

The basic model that I referred to here is a model which Arthur D. Little has developed during the last ten

Has A. D. Little had any previous experience as far as economic impact with regard to the proposed OSHA standards?

MR. FICCAGLIA: I personally am not. Perhaps Charlie --

MR. JENEST: With regard to proposed OSHA standards?

MR. KUCHENBECKER: Yes.

MR. JENEST: No, we have done other analysis studies in the industries, one which received -- it was the petro-chemicals which was rather recently, and that was not at behest of OSHA.

MR. KUCHENBECKER: Not at behest of OSHA, but regarding proposed OSHA standards for the industry?

MR. JENEST: Well, I don't think for industry, but we have done a lot of work for the EPA regarding the air and water pollution control and whether OSHA was involved tangentially or directly, I really can't say.

MR. KUCHENBECKER: One further question.

Did your study that we are discussing here include an investigation of the availability or potential development of engineering controls and work practices that would permit compliance with the proposed standards?

MR. JENEST: No. As we stated, our only task at this time was to do a study of economic impact on the U.S. economy, assuming the complete shutdown of the PVA resin industry. That was strictly our task.

MR. KUCHENBECKER: One further short question.

Did you do any studies of the cost differences between ethylene and acetylene that were produced with VC?

MR. JENEST: Part of the study?

MR. KUCHENBECKER: Yes.

MR. JENEST: None whatsoever.

MR. KUCHENBECKER: Thank you.

MR. KLINE: We have nothing further at this time, Your Honor.

JUDGE MYATT: All right.

Yes, sir?

MR. FRIEDMAN: Marvin Friedman, Industrial Union Department.

Is your Input-Output model published and is there explanation accompanying it?

MR. FICCAGLIA: The models are a proprietary model of Arthur D. Little.

MR. FRIEDMAN: The methodology for updating and provision.

MR. FICCAGLIA: Yes, sir.

MR. FRIEDMAN: And the improvement in detail over and above the CBE model.

MR. FICCAGLIA: If you would like to become a client of ours, we would then discuss it with you.

MR. FRIEDMAN: I take it from the answer that you gave to the Labor Department that your charter is simply to study the impact, the economic impact of a complete shutdown of the industry.

MR. FICCAGLIA: That is correct.

MR. FRIEDMAN: There is no way to analyze the economic

impact in the event of implementation of the proposed standard?

MR. FICCAGLIA: Certainly not a part of this task.

MR. FRIEDMAN: How does your report relate to the proposed standard?

MR. FICCAGLIA: Virtually it assumes if the PVC industry were shut down immediately, what effect might that have on the economy, simply that.

MR. FRIEDMAN: You would come up with different numbers if the charter is different than the industry?

MR. FICCAGLIA: Perhaps it would depend on the charter from the industry.

MR. FRIEDMAN: Let us assume that the charter had been a shut down of ten plants.

MR. FICCAGLIA: A number, we are speculating. But it is beyond the task that we are testifying on today.

MR. FRIEDMAN: Of course, the numbers would be different.

MR. JENEST: With the ten smallest plants in the industry, obviously, the numbers would be different.

MR. FRIEDMAN: Your report says that PVC is very important in the use of production extruded pipe, and that this in turn is important as a segment of the PVC market.

MR. JENEST: Plastic pipe.

MR. FRIEDMAN: Or is it an important part of the construction industry?

I don't think your statement is clear.

but service industries as well, all up the chain to the retail. The number of jobs that would be in that vicinity of a half a million, yes.

MR. FRIEDMAN: And that loss was based upon, at least in part, the assumption you made as to substitutability and the availability of nonavailability of other products, whether then through increase production of through increase imports?

MR. JENEST: The assumption you made after very detailed consultation with the automotive industry, yes.

MR. FRIEDMAN: Did you make any evaluation of the plants that have to be shut down, assuming the implementation of the standard proposed by the government?

MR. JENEST: The PVC resin plants?

MR. FRIEDMAN: Yes.

MR. JENEST: None whatsoever. That was not part of our task.

MR. FRIEDMAN: Do you know anything about the current outlays of the industry?

MR. JENEST: Pardon, would you repeat the question?

MR. FRIEDMAN: Do you know anything about the current outlays of the industry for health and safety purposes, for protection of workers at the worksite?

MR. JENEST: The industry being what industry?

MR. FRIEDMAN: PVC industry.

MR. JENEST: PVC resin industry? No, I do not.

MR. FRIEDMAN: Do you know anything about the

automobile industry and its outlays?

MR. FICCAGLIA: For which?

MR. FRIEDMAN: Health and safety.

MR. FICCAGLIA: Sir, we may know something within ADL, that is not part of the task that we are testifying here on.

MR. FRIEDMAN: Did you make any evaluation of the PVC industry's financial position?

MR. JENEST: We didn't specifically on this assignment, but I have had continuing involvement in the vinyl industry over a long period and have some understanding of that position, but it wasn't part of the task of this assignment. It is just my running knowledge of the vinyl industry.

MR. FRIEDMAN: You made no evaluation, then, of the industry's ability to meet any prospective increased cost that might result from im .ementation of the proposed standard?

MR. JENEST: None whatsoever.

MR. FRIEDMAN: Did you make any evaluation of the technical feasibility with respect to the proposed standard?

MR. JENEST: You mean of the molymer plants and the polymer plants, fabrication plants of meeting the proposed standards?

MR. FRIEDMAN: Yes.

MR. JENEST: This was outside the scope of our assignment. I said that six times.

MR. FRIEDMAN: I would just like the record to be clear that your charter, your charter --

MR. JENEST: I will say it once again, it was outside the scope of our assignment.

MR. FRIEDMAN: And your assignment was to tell this hearing exactly what the situation would be in the event of a total shutdown of the industry.

MR. JENEST: Our assignment, simply stated, was given the assumption that there would be no production of PVC resin in the United States of America, what would be the economic impact of that event on this economy, period.

MR. FRIEDMAN: Do you feel qualified to pass judgment here as to whether that eventuality would come to pass?

MR. JENEST: What eventuality, the shutdown of the resin plants?

MR. FRIEDMAN: Yes.

MR. JENEST: I have no direct knowledge to know whether it is going to happen or not. And I don't know whether industry can meet proposed standards or not. This is beyond my technical competence.

MR. FRIEDMAN: You would have no idea, then, whether in the event that the standards were implemented, whether --

JUDGE MYATT: Sir, don't ask that question. It is perfectly clear they are not even dealing with the

necessary to submit this oral testimony, but if that is spelled out somewhere, could it be submitted?

JUDGE MYATT: Just a minute now. Wasn't this explained tothe prior questioner, the one from the IUD, didn't he take him over the parameters of the study?

MR. COTTINE: Well, it seems to me that just a summary of those parameters would be helpful. It is long cross-examination. It seems to me that there is dispute as to the way I understand it, it is the only parameter that you were given, direction that you were supplied by SPI, the PVC industry would close down if the standard was to be enforced by the Department of Labor?

MR. JENEST: The SPI did not say that the industry would be shut down if this standard were proposed. We assumed that. That was an assumption that if the industry did indeed shut down, what would be the economic consequences.

MR. COTTINE: That is my hypothesis.

MR. JENEST: Yes.

MR. COTTINE: And there was nothing else in the contract except the hypothesis of areas in fact for that matter.

MR. JENEST: Yes.

MR. COTTINE: Okay. One last question.

Could you tell me what the economic impact on the economy would be if PVC workers were to strike and protest against

causes of aircraft accidents. It is also used by NASA to resolve problems arising in very complex areas.

Two specific examples have been brought to mind. One was a resolution of the cause of the fire in which three astronauts were killed. Another example of its use by NASA was in the successful resolution of the causes of a malfunction that arose at the launching of Apollo 13.

I am attaching an unedited set of working notes used by our conference group. The notes represent a collection of data, opinions and speculations that formed the input for the analysis and are submitted for the record so that interested parties can be fully aware of the information upon which the conclusions are based.

In light of the fact that some of the key issues here can only be dealt with in terms of probabilities, as Mr. Beckman noted in his statement, we believe that the information assembled constitutes a contribution to the body of knowledge available, and that it does provide a significant and relevant foundation for reasoned conclusions.

With this premise clearly understood, the following characterizations were established from the available case histories of the aforesaid 13 cases of angiosarcoma of the liver:

1. Each individual case was exposed to vinyl chloride for a minimum of 12 and a maximum of 30 years prior

to diagnosis.

2. Each individual case was exposed to high time weighted average, TWA, exposure to vinyl chloride for a minimum of ten and a maximum of 28 years.

3. Of the 13 angiosarcoma cases, 12 were employed for many years in polyvinyl chloride manufacturing plants and one in a vinyl chloride plant. The latter was employed for a brief period of time in a polyvinyl chloride plant as well.

4. None of the 13 cases were reported to have had acroosteolysis, more commonly referred to as AOL.

5. No agent other than vinyl chloride monomer was [illegible] to the 13 cases.

6. Four of the ten fatal angiosarcoma cases were detected only upon retrospective examination of histopathologic preparations from the autopsy at the time of death.

7. No maintenance personnel such as pipefitters, electricians and the like who could have been exposed to high levels of vinyl chloride monomer were among the 13 cases.

As a result of the characterization of these 13 cases and considering the other available information presented in the attached summary, the following conclusions were reached:

1. All 13 cases of angiosarcoma of the liver were employees who had been exposed over long periods of time to

continuous high levels of VCM. These levels were frequently above the odor threshold and were estimated to be a minimum of 500 PPM TWA and may have been as high as 2,000-4,000 PPM TWA. There is some controversy in the literature as to what the actual threshold level is for the olfactory detection of vinyl chloride.

One source reports 250 to 500 PPM; another uses an approximately 4,000 PPM figure. Moreover, the 2,000 to 4,000 PPM figure is supported by recently generated evidence from very simple experiments demonstrating that the odor threshold in individuals without previous extensive exposure to VCM is approximately 2,000 PPM while the detection odor threshold in individuals with considerable previous VCM exposure is indicated to be approximately 4,000 ppm.

2. The data reported last February by Dr. Maltoni indicates that the development of angiosarcoma of the liver in rats is dose-related.

3. The preliminary data reported in April by Industrial Bio-Test Laboratories, when compared with the Maltoni data for rats, supports the dose relationship conclusion, but also suggests a significant difference in species response. The Industrial Bio-Test mice appear to be much more sensitive than Maltoni's Sprague-Dawley rats, although it should be recognized that exposure conditions in the two cases were somewhat different.

rats and three different species.

MS. HRICKO: Excuse me, though, your statement speaks to the workers.

MR. ERTEL: I understand, madam. May I finish?

MS. HRICKO: Certainly.

MR. ERTEL: As to whether or not vinyl chloride causes angiosarcoma in human beings, I certainly think that there is data which strongly suggests. The facts in this case that are so minimal, that I don't think anyone who is in a position to make a qualified bonafide conclusion based on irrefutable facts. Now, with regard to, if it is causally connected, I believe the statement I made is that we can expect more cases.

I did not use the qualifying phrase in that section of my testimony.

I merely wished to point out that if there is a definite established link in human beings between vinyl chloride inhalation of angiosarcoma of the liver, there are sufficient veteran workers out there who have been exposed similarly to those who have already died.

MS. HRICKO: Thank you. I have two questions for Dr. Kernehl.

First, when was the survey performed that you reported?

DR. DERNEHL: It was a crash survey performed along

the last few weeks just before this meeting.

MS. HRICKO: Did you put together the results of your survey?

DR. DERNEHL: I made out a questionnaire. SPI sent it out because of the number of responses to the questionnaire wishing their input to be anonymous, it came back to SPI. SPI did the addition and -- fed these data to me.

MS. HRICKO: Is the copy of the questionnaire available? Is that part of the testimony?

DR. DERNEHL: It's not on the testimony, you know, but I'm sure a copy can be made available.

[illegible]

DR. DERNEHL: Yes.

MS. HRICKO: Could you also submit for the record [illegible] do this and remain anonymous, those originally polled as to the result of your survey, and that [illegible] the data from workers exposed over a period of time.

DR. DERNEHL: It was all 36 manufacturers, every manufacturer in the United States but one small plant in California participated in the survey.

MS. HRICKO: Then, could you just submit for the record the plants. You said you eliminated some of the plants not having angiosarcoma cases.

They were basically the plants that were too young. Could you define that, define what plants the survey is based on?

DR. DERNEHL: I can tell you --

MS. HRICKO: Not right now.

DR. DERNEHL: I would almost have to tell you right now. We eliminated obviously South Charleston, West Virginia; Louisville, Kentucky; Pottstown, Pennsylvania; and Niagara Falls, New York.

Those plants in those locations were eliminated. Those were the four with cases.

Now, in the others -- I do not know what plants were involved. I know only that plants with less than ten years of experience were eliminated by SPI and the remaining data sent to me.

MS. HRICKO: Of the 1402 workers you studied, how many were alive?

DR. DERNEHL: All of them.

MS. HRICKO: Why did you not study any of the workers in the plants that died?

DR. DERNEHL: We didn't have time.

MS. HRICKO: How can any conclusion be drawn from a study in which the workers who have died-- most likely

included workers who died from the angiosarcoma of the liver are not included in the study, sir?

DR. DERNEHL: Practically all of these plants were also involved in the Tabershaw-Cooper study. In fact, I think all but two were involved in the Tabershaw-Cooper study and in that study they did go back and review the mortality data.

MS. HRICKO: One other question of the other plants that were already included in the same data as the Tabershaw-Cooper, this is in effect is not a new study at all, just the same results of the Tabershaw-Cooper and perhaps with less complete results.

DR. DERNEHL: No, it is not the same because of this particular circumstance we have attempted to fit these people into certain kinds of exposures.

We have applied to their work history both total exposure time and a latent period and we have selected out of this whole group--this particular group who worked long enough or had long enough latent period, they ought to have demonstrated disease if they were going to do it, or certainly they might be expected to demonstrate disease and have not done so.

Also, they have had a sufficiently long exposure time in terms of exposure to vinyl chloride that one might expect disease and it has not appeared.

MS. HRICKO: But any workers from these plants who

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and under typical operating conditions, in those plants without continuous area monitors.

4. Gas chromatography, or where it is available, gas chromatography-mass spectrometry should be established as the instrument in the Reference Method.

5. All results should be recorded as the time-weighted average (TWA) for the period [illegible] tual sampling time.

Thank you.

JUDGE HYATT: Thank you, Dr. Stahl.

(Statement of Dr. Stahl was marked as Exhibit 20-L.)

STATEMENT OF DR. ROBERT D. SOULE, VICE PRESIDENT, INDUSTRIAL HYGIENE SERVICES FOR GEORGE D. CLAYTON AND ASSOCIATES

DR. SOULE: Judge Hyatt, my name is Robert D. Soule of 4221 Marywood Drive, Troy, Michigan. I am currently Vice President, Industrial Hygiene Services for George D. Clayton and Associates, an environmental health consulting organization located in Southfield, Michigan with a branch in Fallbrook, California.

I was present during the testimony and cross examination of Mr. Hyatt on Tuesday on behalf of the Department of Labor, and during the testimony of Mr. Tomashefski yesterday on behalf of the Society of the Plastics Industry. I consider my testimony to be in all essential respects consistent

with their presentation.

I received a Bachelor of Science Degree, Chemical Engineering from Michigan State University in 1963 and a Master of Science in Chemical Engineering degree from Purdue University in 1965.

Between February, 1965 and July, 1970 I was employed by the Dow Chemical Company, with the exception of the first four months, my activities while employed by the Dow Chemical Company were in the field of industrial hygiene -- four and one-half years as an environmental health engineer with the Corporate Environmental Health Laboratory and one year as Senior Industrial Hygienist with the Texas Division in Freeport, Texas.

Since July, 1970 I have been responsible for the industrial hygien services of George D. Clayton and Associates, a private independent consulting firm established in 1954. In my present position I have been responsible for providing industrial hygiene consultive services to a wide spectrum of industries, to various trade associations, to insurance companies, and to several governmental agencies.

I have been personally involved in several contested cases heard before the Occupational Safety and Health Review Commission both as an expert witness for the U. S. Department of Labor and on behalf of industrial clients.

I am a registered professional engineer in the

However, I do believe that it is not unreasonable to expect that such plants could be operated if the working force were required to wear respiratory protection during only a part of the working day.

In this latter case, I would recommend that canister type masks (with proper precautions) be used where the concentration of vinyl chloride permits because of the greater mobility and freedom of motion that is permitted to the wearer. Where the concentration of vinyl chloride in the atmosphere exceed the safe working range of canister type respirators, it is my opinion that only air supplied respirators of suitable design be used.

Thank you.

JUDGE HYATT: Thank you.

Mr. Reporter, Dr. Soule's written statement will be entered into the record as Exhibit 20-H.

(Dr. Soule's statement was marked as Exhibit No. 20-H.)

STATEMENT OF ROGER M. STRASSBURG, DIRECTOR OF ENVIRONMENTAL AFFAIRS, THE B. F. GOODRICH COMPANY

DR. STRASSBURG: Judge Hyatt, my name is Roger M. Strassburg. I am Director of Environmental Affairs for the B. F. Goodrich Company.

I received my Doctorate in the field of organic chemistry from the University of Minnesota in 1950. I have

held positions with the B. F. Goodrich Company during the past 25 years in research, technical management, research and development administration and general administration.

I want to tell you about some of the major objections to portions of the proposed standard which would require that air-fed respirators and self-contained air supplies be worn by workers in an environment where the level of vinyl chloride is detectable.

Since a "non-detectable" level of vinly chloride [illegible] the requirement I just mentioned would mean the full-time use of air-fed respirators, and self-contained air supplies by all employees for their full work turns throughout the vinyl monomer and polymer industry.

This is impractical and even hazardous for reasons I will explain in a moment.

However, employees may use air supplied protective devices while they are cleaning reactors or unloading vinly monomer from tank cars into storage facilities.

In addition, these devices should be available for emergency use if there is a major emission of vinyl chloride in the work atmosphere.

The proposed standard would sanction only four types of respirators. These are:

(1) a positive pressure full facepiece self-contained breathing apparatus;

(2) a pressure-demand full facepiece self-contained breathing apparatus operating in the pressure demand mode;

(3) a combination Type "C" pressure-demand full facepiece respirator operating in the pressure demand mode and a pressure demand self-contained breathing apparatus operating in the pressure demand mode; or

(4) a combination Type "C" continuous flow respirator and a pressure demand self-contained breathing apparatus operating in the pressure demand mode.

These four types of respirators allow only self-contained air supplies. However, in checking with other industries, we have learned that hose supplied, air-fed respirators [illegible] material, welding and spray painting. The hose is usually no longer than 25 feet and generally there is no traffic in the work area.

In our industry, workers who clean polymerization vessels, or polys, also fit this type of activity and the hose, as opposed to a cumbersome air tank, makes it easier to enter the vessel.

With an air tank, the operator would have to enter the vessel and have the tank passed down to him, reversing the procedure when coming out. The hose supplied system has its place, as in this application, but it is not generally applicable to entire plants.

requires full-time usage of personal respiratory protection as part of the occupational health protection strategy."

Are you aware of industries where the use of supplier respirators are continuous and a matter of routine? Eight hours a day or seven hours a day. Did you ever see this?

MR. SOULE: No, not continuous full-time, no.

MR. BELICZKY: Have you ever been in the auto industry, and I'm sure you have?

MR. SOULE: Yes.

MR. BELICZKY: Have you ever seen certain kinds of spray booths--

MR. SOULE: Right.

MR. BELICZKY: --where people use supplier respirators continuously? Have you ever seen a sandblaster use a supplier respirator eight hours a day?

MR. SOULE: I have never seen them use them eight hours a day.

MR. BELICZKY: However long they work. Let's say seven hours a day if they are sandblasting continuously.

MR. SOULE: I'd say it's closer to half-time in those operations where men are required to use that type of device full-time, full-time while in use.

MR. BELICZKY: I have seen them use them full time. And I sort of agree with you that the use of respirators, whether they are for short periods of time or--

MR. HECKMAN: It seems to me the examiner is testifying. He is not asking questions.

MR. BELICZKY: I am asking a question, sir.

JUDGE MYATT: I understand that, but you are also taking advantage of the time to give us the benefit of your thinking.

MR. BELICZKY: I will add very quickly, I am just trying to say, that it is good industrial hygiene practice not to use a respirator, and this probably is true. But there are certain situations--the point I wanted to make, that there are situations--

MR. HECKMAN: Objection.

JUDGE MYATT: Proceed, Mr. Beliczky.

MR. BELICZKY: There are situations that respirators must be worn when there is no engineering practice to control it. And I just wanted to know whether the individual who made these statements is in agreement.

MR. SOULE: Of course. Of course.

JUDGE MYATT: I did not get your answer, sir. What is your answer, Mr. Soule?

MR. SOULE: I said of course there are situations where respiratory protection is necessary.

MR. BELICZKY: Just one little question related to the comments you made on page 11, relative to the hazards of wearing a respirator and where you talk about noise and lack

MR. STRASSBURG: I am sorry.

MR. BELICZKY: What is your present protocol in the B. F. Goodrich plants regarding the use of supplier respirators at your facilities which manufacture polyvinyl chloride resin, and who is issued--which of the workers are issued permanent supplier respirators?

MR. STRASSBURG: The poly cleaners use hose-supplied respirators in cleaning the poly. People who work at the tank farm--you know, where the tank cars are unloaded--either have air packs or hose air-fed respirators available to them and use them.

MR. BELICZKY: So, the third alternative that you forgot to mention is an alternative that you rely on heavily at the present time.

MR. STRASSBURG: Well, like I commented, it was an intermittent use.

MR. BELICZKY: Thank you, Your Honor.

JUDGE MYATT: All right.

Mr. Samuels.

MR. SAMUELS: I have a question for Mr. Stehl of Dow, very short.

Are you familiar with the EOCOM instrumentation?

DR. STEHL: I'm sorry?

MR. SAMUELS: Instrumentation produced by a company called EOCOM. I believe it is a gas chromatograph.

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cast films, or our Plant "B" operation, which is where the extrusion, calendering, and flooring operations are located.

Shortly after the Emergency Standard was issued, the Corporate Industrial Hygiene Department issued detailed instructions regarding type of equipment required and procedures for taking the necessary samples. These instructions are included as Attachment I, and the test method used to evaluate the samples comprises Attachment II.

We have, since then, been monitoring personnel at various work stations in all five plants. The only personnel data indicating values other than "not detected" or less than 1 ppm have been from personnel who unload and sample resin rail cars and [illegible] Henschel [illegible] Plant "B," [illegible].

The highest sample reading we have had from personnel unloading resin cars has been 2.5 ppm. Eight-hour time weighted averages are less than 1 ppm.

Goodyear has put sampling valves on the side of many of our rail cars and is continuing to implement this procedure. This reduces personnel exposure to VCM during sampling.

It is important to note that all of the in-plant results were obtained without any physical or procedural changes to the plants or the equipment except at the Henschel areas.

Accordingly, it is reasonable to conclude that the data, except at that area, is representative of the personnel exposure to VCM in the plants since they began operating.

Except for the improvements being engineered in the Henschel areas, we see no reason to expect the conditions to change other than to improve as the VCM level of delivered resin is reduced.

We have made two changes in the three plants running Henschel mixers to mix compound for pellet production:

1. We have vented to the outside of the plant the exhaust air from the resin weigh system.

2. We have introduced purging air to the inside head [illegible] of each mixer. The purge air is vented from the [illegible] and the data indicates "not detected" or less than 1 ppm. At Calhoun and Merced, the purge air is not vented from the room, and we have recorded sample [illegible] as high as 8.3 ppm.

A third change, started in March, and now ready for installation at all three plants, is to provide for a 10-inch vacuum, vented to the outside on each Henschel mixer. This design change was engineered to completely eliminate the VCM contamination at these areas. It will be completed by mid July.

At that time, there should be no in-plant personnel work stations where exposures to VCM are 1 ppm or over.

Even under present conditions, eight-hour time weighted average exposures at Plant "B" and Calhoun for our Henschel operators are less than 1 ppm. At Merced, where the mixer is in a confined location, we have had one sample of 8.1 ppm and one of 1.6 ppm.

If you were to visit our factories, you would not be surprised that the work stations are essentially free of VCM.

We have generally provided good exhaust conditions at all stations where fumes or dust would represent a potential comfort or health problem to personnel working at this station.

Indicative of this is the fact that we had no citations regarding dust or ventilation resulting from an OSHA inspection of Akron, Plant "B" facility on October 11, 1973.

I think it is significant that even at the largest complex, Plant "B" in Akron, Ohio, where we use approximately 35 million pounds of resin annually, there is no chance for any catastrophic release of vinyl chloride monomer at any personnel work station or elsewhere in the plant. The same is true for the other four processing plants.

The above data were obtained using regular lots of commercially available [illegible]vinyl chloride resin. Even under these conditions, work place levels of more than 1 ppm of VCM are encountered only in the receiving and mixing areas of our plants, and it is obvious that appropriate engineering action

The data teaches us that our range is from a no detectable level on the low side to a 37.6 ppm, that level being present directly above an intensive mixer.

Personnel carbon tube sample on the same area yielded a result of 15.4 ppm.

If I might summarize the results of the nine plants, there were seven plants that ranged in a maximum level of 1.1 ppm to a low of less than .2 ppm.

Two plants represent some higher values, which indicate some additional ventilation needs.

In all cases the downstream portion of the extrusion lines were from a no detectable level to a maximum of 1.7 ppm.

This high level of 37.6 ppm can readily be eliminated by venting the mixer through safe work procedures.

The mixing room areas range from zero ppm to the high of 37.6. And, in connection with this area of the plant operation, it is felt that this area, if it should meet the clean air portion of existing OSHA standard 1910.93, an employee would not be exposed to hazardous levels of vinyl chloride monomer.

Based on all our findings, we join in the view that the processing plants should be excluded from coverage of the proposed standard, since it has been demonstrated that there is no significant exposure for employees in areas other than

Several key conclusions suggested by our work are:

1. Fabricators using flexible PVC compounds -- powders or pellets -- should not encounter VCM exposure problems with their personnel.

2. Fabricators using rigid PVC pellets should not encounter VCM exposure problems with their personnel.

3. Fabricators using dryblend compounds produced by high intensity mixing do not have a VCM personnel exposure problem.

4. Normal [illegible] compounding operations, with conventional plant ventilation, present no VCM exposure problems in the operator breathing zones. Furthermore, subsequent pelletizing operations present no VCM exposure problems to operating personnel.

5. Resin shipment and handling areas require reasonable work procedures and simple ventilation.

These conclusions are based upon facts that we believe are not only reliable, but typical. Furthermore, all of the data was developed by the methodology referenced in Appendix II, and we believe the data to be accurate and reproducible.

Information developed in our applications lab is representative of commercial processing plants since the equipment is of production size and type.

However, data from the applications lab merely

formed a starting point for the testing, which was conducted at commercial production facilities which utilized a broad spectrum of PVC resins and compounds.

Our first conclusion dealing with processing flexible PVC compounds is supported by data presented in Table I and II in the Appendix and can be summarized as follows:

(a) In testing 14 flexible compound samples, we consistently found less than 20 ppm residual VCM. Thus, there is a negligible amount of VCM available for emission into the work atmosphere. (Data pressented in Table I.)

(b) Personnel and area sampling at a flexible PVC tubing manufacturer showed VCM levels of less than a part ppm. The material being extruded was a typical flexible PVC pellet compound. (Data presented in Table II.)

(c) Personnel air sampling at a flexible profile extruder operation showed one ppm maximum VCM on all samples. (Data presented in Table II.)

(d) Personnel air sampling at a flexible blow molder showed less than a part per million airborne VCM on all samples.

The results of our investigations at fabricators using rigid PVC pellets supports our conclusion regarding the absence of VCM in worker exposure areas. This data is contained in Tables III and IV of the Appendix and is summarized as follows.

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(a) While injection molding three-inch couplings on our lab molding machine, area sampling showed 1 ppm airborne VCM. In this test, the pellets had a residual VCM content of 180 ppm and the air sample was taken in the hopper. A later molding trial was conducted using pellets that contained an abnormally high residual VCM concentration of 1,800 ppm. Area and personnel samples obtained while processing these pellets at normal operating conditions showed airborne VCM to be less than 1 ppm. An extreme airborne VCM sample was obtained when the machine was then air purged for ten minutes. This resulted in a concentration of 12 ppm airborne VCM in the [illegible] nozzle area. We do not consider this sample area to be a [illegible] to have typical residual VCM concentrations. (Data presented in Table III.)

(b) A sheet extrusion trial on our lab 2-1/2-inch extruder was monitored for personnel exposure. All samples showed less than 1 ppm airborne VCM and the feed pellets had a residual VCM level of 661 ppm. (Data presented in Table III.)

(c) Air monitoring at a commercial injection molding plant yielded exposure measurements as high as 2 ppm (5 of 18 samples were equal to or above 1 ppm but not greater than 2 ppm; the remaining 13 were all less than 1 ppm). (Data presented in Table III.)

(d) Personnel and area sampling (eight different tests) at a sheet extrusion plant showed VCM levels below 2 ppm. Residual VCM in the rigid pellets was 312 to 390 ppm. (Data presented in Table III.)

(e) On several occasions, we analyzed for residual VCM in rigid pellets, and the resultant fabricated products. This testing showed that only small residual VCM losses occurred during processing. Thus, it is not surprising that airborne VCM concentrations are very low in these operations. (See Table IV.)

Dryblend compounds produced by high intensity mixing typically have low residual VCM concentration -- less than 1 ppm residuals up to 80 ppm.

Table V of the Appendix contains all of the information we have obtained in plants that process these dryblends and supports our view that there is no personnel exposure problem.

A summary of this data is as follows:

(a) A pipe plant, using purchased rigid PVC dryblend, had no area sample containing more than 1 ppm airborne VCM. The dryblends being processed had residual VCM concentrations from less than 1 to 27 ppm.

(b) A pipe plant, using dryblend compound prepared in-house, had no personnel exposures greater than 1 ppm (seven samples taken). Residual VCM in the dryblend ranged

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from 27 to 50 ppm.

(c) A typical flexible film extrusion plant was monitored for airborne VCM. Five air samples were evaluated and all showed less than 1 ppm airborne VCM.

(d) Several rigid extrusion tests were run at our laboratory on commercial-sized equipment. We extruded rigid dryblends (at about 180 pounds per hour) into pipe and rigid foam profile. Area samples showed airborne VCM concentrations to be less than 4 ppm. These samples were taken in the exhaust vent above the machine. Residual VCM in the dryblends ranged from 18 to 40 ppm.

Table VI of this Appendix shows that normal dryblend operations do not present VCM personnel exposure problems. In summary, this data indicated:

(a) Our Deer Park compounding plant produces rigid dryblends with high intensity mixers. Sampling of operating personnel indicated one exposure value of 9 ppm and 12 values of less than 3 ppm. The input resin averages 250 ± 100 ppm residual VCM.

(b) Two flexible dryblend operations were monitored for airborne VCM exposures. Three personnel samples showed airborne VCM concentration less than 1 ppm while one sample gave a 2 ppm result. Residual VCM in the resins ranged from 90 to 629 ppm.

(c) A compounder converting resin to dryblend and

subsequently to pellets was tested. Four personnel samples showed airborne VCM to be less than 1 ppm. Residual VCM in the resin ranged from 72 to 117 ppm.

(d) We have monitored the personnel in the mixing operations at our applications laboratory and all airborne VCM results have been less than 1 ppm -- seven samples. Residual VCM in the resin ranged from 20 to 50 ppm.

Resin shipment and handling may require an alteration of existing work procedures and practices. Table VII of the Appendix contains some limited data showing airborne VCM levels in shipping and storage areas. Comments pertinent to this information are as follows:

(a) The airborne VCM numbers -- up to 150 ppm -- found immediately above the resin in storage silos do not present a hazardous situation since personnel do not work in these areas. Furthermore, these readings are high because of little air movement and because VCM is more than twice as dense as air. If a worker must enter such a silo, the resin should first be removed and the vessel ventilated.

(b) Bagged PVC resin dissipates VCM during storage and therefore airborne VCM can be expected in ambient air in warehouses. We found airborne VCM levels up to 8 ppm in the immediate vicinity of freshly bagged PVC. Simple ventilation in resin sotrage areas will eliminate even these trace concentrations of airborne VCM.

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(c) Monitoring inside closed bulk rail cars and trucks for airborne VCM has shown high concentrations in these confined areas. These concentrations are the direct result of having very small air volumes and no ventilation. The potential VCM exposure problem in these cases can be effectively and easily dealt with by venting prior to any employee's entrance.

We believe the data I have just reviewed demonstrates that PVC fabricators and compounders using materials which contain less than 0.1 percent (1,000 ppm) unreacted vinyl chloride monomer are not exposed to any significant airborne VCM hazard and should [illegible] be exempt from coverage under the final regulations.

Given the extremely low levels of VCM found in ambient air in plants using resins containing unreacted monomer in ranges up to 1,000 ppm and, in some cases, even higher, we can see no real need for the SPI recommendation that the exemption level be lowered to 100 ppm in 1977.

Thank you.

tws fls.

Most recently, as Manager of National Accounts, I was concerned with the requirements of multi-plant customers, and on my present assignment, I am involved with general industry problems such as presented by the proposed OSHA standard on vinyl chloride.

I have prepared this statement to be submitted on behalf of the vinyl chloride (VC) and polyvinyl chloride (PVC) Producers Committee of the Society of the Plastics Industry (SPI).

[illegible] will demonstrate that workers in PVC processor plants are not normally exposed to detectable levels of vinyl chloride and [illegible], levels of [illegible] [illegible] [illegible] rent [illegible] to the proposed permanent standard.

Processors handle and process PVC resins, PVC premixed compounds, PVC latexes (PVC suspended in water), and PVC resin dispersed or dissolved in plasticizer or solvents. There are at least 3,000, and possibly 4,000 such processing plants in the United States.

Generally speaking, these plants are owner managed small businesses. The average number of workers per shift is estimated to be ten to 20 in a typical PVC processing plant. These typically small companies, which are a most important segment of the plastics industry, generally do not have the

particular number, and above that number respirators would be required in other stages of vinyl chloride production and PVC production -- would you suggest that a different number be applied to the fabricating industry with respect to the requirement for respirators, or would you suggest to us that the number be the same for you as well?

MR. WEAVER: I guess until you have a chance to study at least the data I presented, if you have done a proper job of ventilation according to a standard that already exists, you should not have any detectable level of vinyl chloride in the workplace, in the processing plant, and therefore I see no need to even talk about respirators.

MR. KLEIN: I assume, then, that you feel that OSHA should in some way or another, whether it be through this standard or through an existing standard, compel fabricators to get below 1 ppm; is that correct, sir? Gentlemen?

MR. WEAVER: I don't think you should even have to go around monitoring to determine if he is at one part or one-tenth or no detectable levels. If he does his job of exhaust ventilating that he should on any high processing equipment, there won't be any monomer there to measure.

MR. KLEIN: What would you suggest with respect to employers who don't install the appropriate venting equipment?

MR. WEAVER: Then they are in violation of 1910.93

already

MR. KLEIN: Do any of you gentlemen see any value whatever with respect to medical examinations? Do you think they are completely meaningless in your operations?

MR. SMITH: With respect to the processing plants?

MR. KLEIN: Yes, sir.

MR. SMITH: I see no need for any medical beyond the mixing room area -- the worst condition.

MR. KLEIN: Do you feel it would serve any purpose to find out whether there was any liver dysfunction at lower than [illegible]?

MR. SMITH: I am sure, for data's sake, it would be [illegible]

MR. KLEIN: And if the liver dysfunction was discovered, do you think it might be able to help an employee if he had medical examinations given to him?

MR. SMITH: Well, I am sure that everyone needs a medical examination periodically. I am not sure what we are driving at. I don't quite follow you.

MR. KLEIN: Mr. Weaver, I have a question for you. Do you consider the resins which you use capable of releasing detectable levels of vinyl chloride?

MR. WEAVER: Yes, I can very quickly run down through the table -- if you have it open to page 4. The first one, used in floor covering, would have on the average about 25 ppm of

extremely low, and when we have then followed those materials through the processing history, we have essentially found nondetectable levels. I find it very hard to believe that the man could have been exposed to detectable levels of VCM.

MR. LASSITER: Thank you.

MR. [illegible]: We have nothing further at this time, Your Honor.

JUDGE WYATT: All right. Mr. Beliczky.

MR. BELICZKY: I would like to address the first question to Mr. Becker.

Your presentation and the tables that were offered were of great interest to me. I just wonder that in the operations which were evaluated, would you consider that the local exhaust available in the various operations was in conformance with the recommended ventilation control, as would be recommended by the American Conference of Governmental Industrial Hygienists, or in good ventilation in conformance with just generally good industrial hygiene recommendations?

MR. BECKER: I would say that the ventilation in the examples that I gave was of good quality, yes, sir.

MR. BELICZKY: Are you aware of the fact that there are plants in this country who use the polymer to make products who have absolutely no ventilation?

MR. BECKER: Yes, sir.

MR. BELICZKY: The samples were collected utilizing

MR. BELICSKY: Thank you.

JUDGE HYATT: Are there any other questions?

MR. BECKER: Could I add a comment to that? We conducted an experiment specifically designed to answer this question.

We found if you put it on a charcoal, it can last there for two weeks. We feel very confident of that. We would make that information available if you like.

MR. KLEIN: Would you, please? We'd appreciate that.

JUDGE HYATT: Mr. Samuels.

MR. SAMUELS: Mr. Weaver, did I understand you to say that the problem of meeting the proposed standards could be met with [illegible] ventilation methods and controls?

MR. WEAVER: Yes, sir.

MR. SAMUELS: And in response to the question from the government, you said in the case of someone who did not provide these controls, that would be in violation of the proposals, is that correct?

MR. WEAVER: Violation of an existing standard, yes.

MR. SAMUELS: Then it means, I take it, that some standard control to require such ventilation is necessary.

MR. WEAVER: I would certainly think so.

MR. SAMUELS: I am glad you have the integrity to disagree with Mr. Heckman. Thank you.

MR. HECHMAN: I object to that statement being on the record without an explanation, Your Honor. I also ask that it be stricken as malevolent.

JUDGE MYATT: I am not going to strike it. Your objection is noted.

MR. HECHMAN: I would like it explained. I don't understand what the disagreement was.

JUDGE MYATT: Well, I don't want it explained.

Yes, ma'am.

MS. HRICKO: The first question for Mr. Beebe.

How many plants in your division would be covered by the OSHA permanent standard for vinyl chloride?

MR. BEEBE: All five.

MS. HRICKO: How many of these plants would have to close down if the proposed permanent standard went into effect in October?

MR. BEEBE: I don't think any of them would.

MS. HRICKO: Thank you.

In your testimony you stated that there was an OSHA inspection October 11, 1973, and that there were no citations regarding dust or ventilation. Was your plant monitored for vinyl chloride at that time?

MR. BEEBE: No.

MS. HRICKO: So that this paragraph which starts off, that the work stations are essentially free of vinyl

MR. CONNOLLY: Pardon?

MR. [illegible]: I don't believe you could get the resin.

MR. WEAVER: Mr Smith needs much more resin. I will let him answer.

MR. CONNOLLY: I would like each one of you to [illegible] because I don't want the record to be [illegible] the prior question.

[illegible] inside the United States?

MR. WEAVER: [illegible] would not be able to obtain [illegible] PVC resin inside the United States who operate processor plants. And based on my knowledge of the tightness of supply [illegible] to make vinyl chloride monomer [illegible] definite shortage of vinyl chloride monomer, and PVC resin worldwide.

I am sure, as the Japanese have been doing for the past [illegible], they would not share it with PVC processors.

MR. CONNOLLY: The gentleman from Diamond Shamrock has already indicated he can't. Mr. Smith?

MR. SMITH: I have no earthly idea where we would get it.

MR. CONNOLLY: Mr. Beebe?

MR. BEEBE: I wouldn't know where to get it.

MR. CONNOLLY: So if you could not get the resin,

of PVC which we are currently producing at a rate of 240 million pounds per year with 500 million pounds projected for 1975 and beyond.

The consequences of the latter option have already been reviewed by the SPI. I want to reiterate on behalf of Tenneco that discontinuing the manufacture of PVC would have tremendously disruptive effects on the defense, wire and cable construction, automotive and the phonograph record industries.

It is neither safe nor feasible to place vinyl chloride workers in respirators for the full duration of a work shift. However, given the serious nature of available scientific and medical evidence regarding potential human health effects of vinyl chloride inhalation, management, union leadership, the Federal government, and the medical community must, in concert, agree that the only conceivable course of action for industry is the maximum feasible reduction of human exposure to airborne concentrations of vinyl chloride monomer. Though a no detectable standard is not feasible, it is, nevertheless, incumbent upon the industry to take every technologically and economically feasible step to reduce levels of ambient vinyl chloride.

I am accompanied by Dr. Paul Lobo, Director of our Technical Group for Tenneco's Organics and Polymers Division, and by Mr. Philip Scarito, Works Manager of our

Burlington, New Jersey, facility. They will supplement my general presentation with a more detailed analysis of the proposed standard's lack of feasibility from the engineering and plant operations viewpoint, while pointing out the steps that Tenneco has taken or will take to reduce worker exposure to vinyl chloride. I shall outline to you the elements of a position which Tenneco considers to be feasible and which incorporates the best work practices within the shortest possible period of time. It is appropriate at this time, however, to profile briefly Tenneco's facilities and work force.

Tenneco is involved in all three stages of production associated with the various polyvinyl chloride manufacturing operations. Our Pasadena, Texas, facility produces vinyl chloride monomer. Our Flemington and Burlington, New Jersey, plants manufacture 36 different resins through a number of complex polymerization processes. The various resins manufactured require different operating procedures and involve different types of technology. The potential vinyl chloride exposure problems, therefore, also differ widely from one process to another within the same site.

Further, at Burlinton we process resins with other chemicals and additives to form semi-finished vinyl compounds for subsequent fabrication. Our facilities at Nixon and Carlstadt, New Jersey, and at Newton, Massachusetts, process

vinyl chloride resins into a variety of fabricated products both rigid and flexible. At Tenneco, 15 employees are currently involved in monomer production, 343 in the manufacture of polyvinyl chloride resins, and 456 in the manufacture of fabricated products. Tenneco's production capacity for polyvinyl chloride is about to be significantly augmented by the opening of a new facility at our Pasadena, Texas, chemical complex, using a new large reactor technology. This facility will employ an additional 60 individuals.

Tenneco has researched the work history and cause of death of the 20 persons, out of a total of 1,020 personnel employed over the course of our 17 years of operation, who have died while still employed at our monomer and polymer facilities. None have died from angiosarcoma of the liver. Tenneco participated in the epidemiological survey of the industry conducted by Tabershaw-Cooper Associates whereby cause of death was researched for certain former Tenneco employees. Again, no other Tenneco employee, found by the Tabershaw-Cooper researchers, had died from cancer of the liver.

The vinyl chloride industry has grown during the last 30 years from production at the multi-hundred-million-pound level to today's five billion pounds. During this same period, employee exposure to vinyl chloride has been drastically reduced because technical advances have enabled

Massachusetts Institute of Technology and a doctorate in chemical engineering from the University of Michigan. I have had 19 years experience in the chemical industry in the field of research and development, engineering and technical management. Eight of these years were spent developing commercial processes from the laboratory through the pilot plant to commercial plant design and start-up.

Based on the presently available technology, it is not feasible for existing polyvinyl chloride facilities to meet the proposed OSHA standard through engineering changes. Further, the proposed standard cannot be met through any combination of engineering changes and altered work practice methods, without the use of respirators 100 percent of the time. As I understand it, the proposed standard does not contemplate use of respirators 100 percent of the time. If the standard were to result in the full-time use of respirators, as Mr. Fath has pointed out and as Mr. Scarito will detail, we are convinced that this would not be a practical mode of operation. I will defer to Mr. Scarito on the respirator and work practices questions and focus my remarks on the engineering implications of the proposed standard.

Tenneco's polymer facilities range in age between five and 17 years. Our Flemington, New Jersey, plant was originally constructed in 1957, and extensively rebuilt in

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1969. It produces approximately 85 million pounds per year. Our Burlington, New Jersey, facility consists of four distinct plants having a total capacity of 150 million pounds per year. Two of these make PVC resins, homopolymers and vinyl acetate copolymers by the suspension process, and were built in 1961 and 1964, respectively. Plants making resin by the dispersion method were added in 1965 and 1969. A new large suspension resin plant is scheduled to begin operations at our Pasadena, Texas, facility in the fall of 1974. It will produce approximately 250 million pounds per year.

All our plants currently in operation were constructed based upon the best knowledge of vinyl chloride processing available at the point in time when they were built. None were built with the knowledge that exposure of vinyl chloride monomer may constitute a serious health risk to workers beyond the known anesthetic and flammable properties of this gas. Although up-to-date engineering practices were used in their design and construction, there exists no practical, quick corrective means to bring these facilities into conformance with a standard of no detectable level of VCM in the plant areas. In this conclusion, I include even our most modern facility that is expected to begin operation in Texas this coming fall.

In the design of PVC polymerization facilities, a

batch or discontinuous chemical process is employed by [illegible]. Such a process [illegible] after one or more [illegible] the removal of water, un- [illegible] from the polymer after the [illegible] and drying [illegible] All of the [illegible]

[illegible] considerable distances. [illegible]

[illegible] process carried out [illegible]. It is easier to reduce [illegible] presented by the [illegible]

[illegible] worker exposure to

vinyl chloride monomer. First, the monomer usually arrives at the polymer facility by tank car or by truck and at this unloading stage, some exposure is unavoidable since transfer hoses must be hooked and unhooked. Workers currently wear air-supplied respirators for these unloading tasks. However, because of the coupling and uncoupling steps involved, emissions in this area can contribute to the general levels of VCM on the site. We have changed our unloading techniques to reduce these emissions considerably, even though these changes represent a lowering of operating efficiency. We are not able, however, to eliminate entirely the escape of some VCM in this area.

Second, in all of our existing plants the walls of reactor vessels must be cleaned by workers since deposits of polyvinyl chloride form on them during the polymerization process. These deposits prevent the heat, which is released during the reaction, to be removed through the wall of the vessel, thus interfering with the process and creating a potential safety hazard. Further, if these deposits are permitted to remain, such safety devices as relief valves may become clogged posing a further threat to workers' safety. Additionally, if a clean reactor is not used, product quality can be degraded to a point where it becomes useless to the plastic processor.

We have found means to increase the number of

batches that can be processed before it is required that a worker enter the reactor to clean it. Frequency of reactor entry can be further reduced through employment of certain cleaning technology which Tenneco is currently developing, and our future plans to minimize worker exposure presuppose installation of improved cleaning processes or procedures. However, even with these processes, it is very likely that periodic vessel entry will be required to assure that the mechanical internals are in working condition and emergency [illegible] have not become blocked by polymer and thus rendered inoperable.

A third source of worker exposure is leakage from mechanical equipment, that is, compressors, pumps and valves. In the design of our facilities, sound engineering practices were used to select such equipment; however, this was in accordance with known technology, exposure limits then considered safe and the nature of the processes utilized. Contrary to the claims that some have made, this leakage cannot be eliminated through installation ofa few readily available substitute valves and pumps.

There do exist some low-volume pumps that have been field-proven which can help "tighten up" certain stages of our operations. These pumps will be installed as part of our program to minimize worker exposure. For higher volume applications, there are available so-called

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canned pumps which might reduce vinyl chloride leakage but they have not been tested in PVC plant applications such as slurry service. We cannot be confident of their feasibility in our installations at this time.

The fourth and most significant amount of vinyl chloride escape results from the drying stage of the resin production process. The drying stage is a necessary facet of suspension and dispersion processes used in the Tenneco plants. Some of our dryers are gigantic rotating kilns, 50 feet long and 10 feet in diameter, which use immense volumes of air, 30,000 cubic feet per minute or more, to remove water from the resins. During this processing step, quantities of residual monomer not removed in the earlier stripping stage are removed from the polymer and some of the monomer escapes into the plant site area.

One approach which has been suggested to remove VCM from the ambient air is adsorption by activated carbon. This is considered wholly impractical where large volumes of air and small concentrations of VCM are involved. In our new Pasadena plant, we have included carbon adsorption to recover VCM from two small process streams, neither of which contains air, but even this limited application has yet to be tested on a commercial plant scale.

Because of the factors I have just described, it is not feasible by engineering changes utilizing presently

available technology, to modify our existing plants to meet the proposed standard, nor can a combination of work practices and engineering changes achieve that result. However, steps can be taken to reduce employee exposure to vinyl chloride. With these steps, Tenneco hopes by October 1976 to reduce vinyl chloride monomer exposure levels to 10 parts per million (time-weighted average) with a ceiling excursion of 25 parts per million.

Our program includes installation of:

A very extensive sequential area monitoring system to insure conformance and to indicate excursions;

New, low leakage pumps;

Equipment to minimize reactor entry for cleaning;

Ventilation equipment totally beyond the scope of our current operation; and,

An extensive manifolding system so as to permit utilization of respiratory equipment where needed.

It will also include the isolation of certain key areas from worker exposure and extensive addition of processing equipment to attain stripping and monomer recovery efficiencies far beyond our present capability.

It should be noted that these extensive modifications dictate the prompt placement of orders for such equipment since current delivery and installation schedules range upwards of two years. While we have already ordered some

of this equipment, it must also be realized that design specifications cannot be made until a permanent standard has, in fact, been defined. Such design specifications do not exist for the proposed "no detectable" level.

In addition, Tenneco has under way significant research and development efforts already mentioned by Mr. Fach, the goal of which is to eliminate the highest possible percentage of monomer from the resin prior to the drying stage. To date, our laboratory studies have shown that monomer levels in certain of our resins can be reduced substantially below the 0.01 percent level, which is 100 ppm. Our research and development program is currently geared toward [illegible] into the commercial plant. These improved techniques will require the further addition of equipment which is subject to the same lengthy delivery schedules.

This development effort, if successful, should result not only in a drastic lowering of the residual monomer content in our resins, but also should aid in greatly reducing the amount of monomer released in the drying stage. This will aid in reducing monomer levels in the PVC plant site area. In addition and most important, the downstream vinyl processors will benefit from these lower contained monomer levels in the resin, resulting in the substantial elimination of exposure to the hundreds of thousands of

full face respirators reduce some of the problems of the limited field of vision, hearing, and claustrophobia, they still present the problems of accidents from tripping, constriction of vertical vision, and the possible injury to throat and lung tissues from extended use.

The drafters of the proposed standard appear to have recognized the [illegible] I have outlined. The standard states: "Respirators shall be used only in cases of emergency... and ...respirators may not be used in lieu of feasible engineering controls or work practice methods." Since, as has already been discussed, engineering controls and work practice methods cannot yield a no-detectable level environment, [illegible] 100 percent of the time of air-supplied respirators, an outcome that OSHA and industry apparently agree is not acceptable.

Tenneco has undertaken the following steps to reduce ambient vinyl chloride in plant areas through use of work practices and tolerable maximum use of respirators:

(1) Taking siding from the building--some of the buildings;

(2) Added ventilation;

(3) Installation of manifold air-supplied system to completely cover all of the reactor building areas at all levels as well as other necessary plant areas;

(4) Issuance to each worker of a full-face air-supplied respirator for reasonable use when necessary;

(5) Improved stripping of residual monomer from the wet slurry and thereby reducing vinyl chloride in the air during subsequent processing;

(6) As an interim step, prior to the installation of sequential monitoring, we have introduced the use of automatic vapor analyzer monitoring to identify minute leaks not otherwise detectable; and

(7) Improved work practices relating to the [illegible]

[illegible]

Thank you.

JUDGE WYATT: All right. Mr. Klein?

MR. KLEIN: [illegible] a question, if any of you people feel competent to reply to it, you just do it, please.

Do you have with you today your measurements in monitoring that have been taken at your various plants?

MR. FATH: No, we do not have them with us, Mr. Klein, but they are available.

MR. KLEIN: Can you tell us, at each of your plants, representative figures with respect to worker exposure, as you remember them?

MR. FATH: Based on the personnel monitoring data that we now have, our figures fall into various categories,

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in operation. We do have there a monomer producing facility, a small one, and in that plant our levels are considerably lower, mostly in the area between 0 and 10 parts per million, due to the fact that it is a continuous process and it is totally outdoors.

MR. KLEIN: Have you been able to project at the plant under construction approximate exposure levels to employees there?

MR. FATH: We feel that that plant will be able to meet the ultimate level that we have proposed as a limit of feasibility sooner than the remainder of our plants, for which we have projected a two-year level to achieve that point.

MR. KLEIN: What technical controls or work practices will exist at the new plant that would account for the difference in terms of your lowering the exposure levels?

MR. FATH: The fundamental difference in that plant, aside from the fact that it will be a brand-new plant, with new equipment not subject to prior wear, is the fact that it will have fewer but larger reactors and that, due to its southern location, will have a larger percentage of its total equipment located out of doors.

As to the work practices, perhaps Dr. Lobo can add to it.

DR. LOBO: There will be two other elements which

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MR. KLEIN: Now, directing your attention to the improved ventilation systems, are there ventilation systems in the new plant that do not exist in your older plants?

DR. LOBO: No, there is nothing different in that aspect. What we have done in recent years is to increase the number of air changes per hour in our buildings. And our new plant will be designed on the same criteria. Also, as Mr. Fath mentioned, the new plant will be in the south and consequently it is generally open-air construction. This is a problem in the plants in the north, because they are all constructed inside buildings.

MR. KLEIN: Is there some major problem involved in ventilation control, using ventilation as a control?

DR. LOBO: In terms of moving enough air to meet some lower level of VCM ---

MR. KLEIN: Yes, in terms of removing the monomer.

DR. LOBO: I think in some cases we are approaching infinity in terms of the amount of air we would have to move to have an undetectable level....I think you can roughly calculate, maybe it is more academic--but one pound of VCM, if diluted with air uniformly would cover an area of 30 acres 15 feet high--and would equal one ppm.

MR. KLEIN: What technology in recent years have you used to control leaks better than you had previously?

DR. LOBO: We have upgraded our equipment, but we

haven't been able to really solve the problem. We have most recently used our ovameter to determine the flanges, pump-packing, compressors and so forth, which are leaking--and giving those more maintenance. We are looking at adding pumps which will not leak or leak at lower levels, evaluating different types of valves which we feel might leak less.

But this is a development program.

MR. KLEIN: Now, I understand that you have dramatically reduced the levels of exposurevery recently, is my understanding correct?

DR. LOBO: I don't think that was said.

MR. KLEIN: No, I have just heard that; I just want to know if that is an accurate understanding on my part.

DR. LOBO: We have made good progress, but I think we are talking about coming down from perhaps 200 ppm, in some <u>areas</u> now where we are 25 and 30, which has allowed us to operate in those areas without the use of the respirators. We have been pleased with our performance, but it is a long slow job.

MR. KLEIN: Other than the controls, practices, etc., that you have indicated today, are there any other means used to reduce the level of exposure of employees?

MR. FATH: Well, of course, we have used respirators a good percent of the time and have put certain operations

34 on a standard respirator use procedure.

MR. KLEIN: How many hours a day do these employees wear the respirators?

MR. SCARITO: It varies, of course, with the jobs. It would range anywhere perhaps from five minutes for some employees to as high as perhaps an hour to an hour and 15 minutes at a time for other employees.

Is that what you meant?

MR. KLEIN: Yes. Now, at times when they are not wearing the respirators, are these employees in the ambient air that contains the vinyl chloride?

MR. SCARITO: What level of vinyl chloride?

MR. KLEIN: Any level.

MR. SCARITO: Well, yes, we have, as we have indicated before, there are measurable levels of vinyl chloride throughout the entire plant. And the employees are there.

MR. KLEIN: What level do you use as your cut off?

MR. SCARITO: Well, currently 50 is the cut off point at which we require mandatory use of respirators.

MR. KLEIN: Are there levels in your plant where the levels are below detectable level, as we define it in the proposal?

MR. SCARITO: Below no detectable?

MR. KLEIN: As defined in the proposal.

MR. SCARITO: I don't know of any area in the plant

hearing now, but I would make a request to you: if you would, could you indicate to us the various job classifications and, as closely as you can, indicate what type, what the level of exposure is as to these job classifications and whether it is an intermittent type exposure or a general exposure?

I really don't want to take the time of the hearing now, but I think that explanation would be very useful to us.

MR. FATH: I presume that these are the compliance records that we now have at our plants?

Let us say, cross-referenced by operator classifications?

MR. KLEIN: Yes, I think so.

If you could do that, we would appreciate it.

MR. FATH: Yes, we will make that available.

MR. KLEIN: Thank you.

Which job classifications are presently using respirators at your PVC plants?

MR. SCARITO: There, the reactor operators for certain short-term operations, are using respirators. People who unload our monomer from the rail cars to our tanks wear respirators. Our cleaners, our vessel cleaners wear respirators. Our maintenance people on certain specific jobs where they may come in contact with residual vinyl chloride, wear respirators.

two years. However, we will only know that once we operate.

MR. SAMUELS: But in general you would expect that newer plant in the south, where they might be open, oper plants might be of a year's period of time?

MR. FATH: Not wishing to speak for other technologies, I don't think you can necessarily draw that conclusion because while that location favors lower levels, the quality of the engineering and frankly the type of the product produced, also has considerable influence.

Let me add there that as I indicated, we manufacture some 36 different resins. Our plant in [illegible] produce only three of these types.

Therefore, other technologies, whether they are located north, south, or elsewhere, are not subject to the same engineering skills and improvements as that particular plant is.

MR. SAMUELS: I see. But in general you would, would you subscribe to the concept that the fewer the reactors, the larger the reactors that might be outdoors, plus supplying reactors with monomer by pipeline, those are factors which reduce and make more feasible the reaching of any level.

MR. FATH: That is indicated, yes.

MR. SAMUELS: I have a question for Mr. Lobo, but

perhaps you might want to refer to someone else in your panel.

I referred to you because you mentioned that the capital expenditures would be $10 million.

Is this for all plants plus the contemplated expansion in Pasadena?

MR. LOBO: Yes, this is our very preliminary guess, what the capital requirements might be to reach the ultimate level that we can get to by 1976.

MR. SAMUELS: So it is not based on a hard cost basis?

MR. LOBO: That is correct.

MR. SAMUELS: Okay.

[illegible] you just had a gut feeling that it was all the plants involved?

MR. LOBO: No, it has been broken down by plants, again, based on our best estimate at this time.

MR. SAMUELS: Given the current price of resin, I don't know what you charged. [illegible] Yesterday, one of the fabricators said he was paying 35 cents a pound. Can I ask you currently what your prices are?

MR. FATH: Certainly. I believe the reference yesterday to 32 cents a pound was referred to plasticol for resin, which is of a different type and more costly to produce.

Our general-purpose resins, our current price is 17 cents a pound.

MR. SAMUELS: Now, looking at this $10 million capital expenditure, and I realize that there are other costs, labor costs, et cetera, looking at it, could you calculate that cost as a percentage of the sales price of the resin which you just established -- did I hear you right -- you said 17 cents?

MR. FATH: Yes.

MR. SAMUELS: What percentage of the sales price would this capital expenditure constitute, roughly?

MR. FATH: I believe it can be calculated, but it depends on how many pounds.

MR. SAMUELS: How many pounds do you --

MR. FATH: I don't think one can come up with any single percentage figure.

Let us also include here, the ten was upward of ten. We are not currently sure that that particular number is a high enough number. It is an order of magnitude number that we are quite convinced will not go below; we may go substantially above.

MR. SAMUELS: Would you hazard a guess about a range?

MR. FATH: That is entirely dependent upon the final standards that will be issued, because that number and any

MR. FATH: Well, nowheres in our testimony--and I would like to reiterate this--have we been guided by those economic considerations. That is to say, we believe in investing the necessary funds to reach the most feasible--the lowest feasible level.

So, we have not taken that consideration into account in coming up with lowest technologically feasible levels.

MR. SAMUELS: Thank you.

MR. COTTINE: Mr. Fath, do I understand your testimony correctly that there is a new facility under construction and another facility under expansion, or is there only one facility that is being developed?

MR. FATH: There is only one facility under construction.

MR. COTTINE: And that is the Houston facility?

MR. FATH: Yes.

MR. COTTINE: When did your engineering planning commence for that particular facility? The year.

MR. FATH: I believe it was 1972.

MR. COTTINE: When was the design and operational program completed? In other words, that study and final plans completed.

MR. FATH: Well, we broke ground in August of last year, 1973.

MR. COTTINE: August of '73. Did you make

In terms of levels.

MR. FATH: Right. The EPA data, I don't believe are published as yet.

MR. COTTINE: You haven't received it?

MR. FATH: No, our informal understandings are that the parimeter lines are one part per million or below. We do have the data for our Pasadena monomer, they are on the order of .3 parts per million.

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MR. COTTINE: And the OSHA inspection, have you received the sample data sheets back on those?

MR. FATH: No, we have not. We have had extensive inspection of our own data and records.

MR. COTTINE: I assume in response, to the other response, it will be submitted for the record?

MR. FATH: Certainly.

MR. COTTINE: Would you also submit the OSHA and EPA monitoring levels?

MR. FATH: We will be glad to when they are received.

MR. COTTINE: Obviously you have a monitoring program. Do you have a medical surveillance program?

MR. FATH: We do.

MR. COTTINE: Have you established any ppm levels or goals recently, since the establishment of the emergency temporary standard?

JUDGE MYATT: All right, Mr. Fleming?

MR. FLEMING: Thank you, Judge Myatt.

I am Richard Fleming, Group Vice President of Air Products and Chemicals, Incorporated. I am responsible for the chemical group of our company, headquartered at Valley Forge, Pennsylvania.

Testifying with me today are Mr. John G. Barr, Technical Manager, Manufacturing, on my right, and Doctor [illegible], M.D., our consultant on vinyl chloride monomer medical matters.

Also here with me today are Doctor A. Ross Adams, [illegible] Division, Mr. [illegible], Vice President of Manufacturing, and Mr. Joseph Sebastianelli, Attorney.

Air Products operates two plants for the production of polyvinyl chloride, based on the suspension process, located at Pace, Florida and Calvert City, Kentucky. Combined capacity of the two plants is approximately [illegible]00 million pounds per year, or approximately 3.5 percent of the total PVC industry.

Air Products also operates a PVC compounding facility at Calvert City, and a small plastic fabrications plant at [illegible]town, New Jersey, Costa Mesa, California, Durant, Mississippi, and Homestead, Pennsylvania.

In addition, we now operate a plant at Calvert City

for the production of a different class of polymers sold as water emulsions, which also use vinyl chloride as one of several monomers for a portion of its output. And we have a second plant of this type now under construction at South Brunswick, New Jersey.

The total number of employees engaged in all of these operations, including service, support and management, is about 600.

Air Products is a non-integrated producer of PVC; we purchase all of our own materials, and are only very slightly integrated forward into fabrication, using less than two percent of our PVC production.

We are about tenth in capacity among PVC producers, and a relatively large proportion of our output is in special types of polymers. Our PVC plants have been operating since 1957 and 1959, each coming to Air Products as part of acquisitions of larger business -- the Florida plant in 1969, the Kentucky plant in 1971.

Air Products has participated in industry studies of health hazards of VCM and will continue to do so. Our own medical examination program, which will be discussed later by Doctor Kotin, has covered approximately 460 present employees.

We have also studied the mortality experience of all employees who have worked in these plants since their

[illegible] since 1961. Of these, 13 are in the U.S., found among the employees of 15 VCM plants and 36 PCV plants.

Of the thirteen cases, seven have occurred at one PVC plant and three at another. A U.S. total of four such PVC plants [illegible] had no cases.

There are [illegible] plant worker populations who have no record of angiosarcoma although they have lived through [illegible] exposures well above levels no one would tolerate [illegible] of current information.

There is a considerable body of animal exposure data to show decreased hazard with decreasing exposure levels [illegible] human experience in the plants reported [illegible] at the February hearing held by the Department of Labor has shown no incidence of angiosarcoma among its workers from long-term average exposures of between 100 and 300 parts per million, TWA.

Air Products' own health studies show one case of [illegible] and no other health problems relating to exposure in our operations to date.

Although exposure levels in fabricating plants have generally been very low, exposures in a few jobs in these plants have historically probably been on the order of 15 to 25 TWA. Until the recent announcement of the GE wire-coating case and the case of the accountant at a vinyl sheet-producing plant, there were no reported angiosarcoma cases among fabri-

cation plant employees.

As we have heard in testimony at this meeting, any relationship between these cases and exposure to VCM remains conjectural at this time. Careful study of the very large body of human experience already available in the history of PVC fabrication operations is clearly warranted and can shed important light on the hazards of relatively low-level experience.

Exposure levels in VCM plants are generally considerably lower than in PVC plants, because of the continuous process technology of the monomer operations and the generally outdoor construction of these plants.

Only one angiosarcoma case has been found among VCM workers in this country, and this man is reported to have worked on very high-exposure tasks relating to sampling and catalyst tube cleaning. He also worked in PVC for the final year of his working life.

All of these considerations lead to the idea of a relatively safe but readily measurable level of VCM in a work environment.

We therefore support the proposal for a 25 TWA exposure level to become effective October 5, 1974, that was part of the SPI recommendation. As we will show later, we believe that this level is also feasibly attainable, though a difficult and expensive one to continuously meet 100 percent

[illegible] would hope to do under such a regulation.

[illegible] levels proposed for later achievement by SSI [illegible] difficult and much more speculative as to [illegible] at this time, in our view. This, too, will be [illegible] by Mr. [illegible].

[illegible] that is required by the new [illegible] below current achievement confronts a producer [illegible] alternatives.

[illegible] does not meet the standard, he can [illegible] business. The economic consequen- [illegible] of this on the producer and his specific employees are [illegible] depends upon what [illegible] sources of material they can find. SBI testimony [illegible] has covered this in some detail.

[illegible] the producer may make changes involving capital [illegible] otherwise to bring his operation into compli- [illegible] on the severity of the standard, this will [illegible] fundamental and expensive changes, and thus [illegible] times, and may reduce output, although not [illegible] entirely.

[illegible]: he may decide to replace his current [illegible] designed to meet the new standard. This [illegible] requires the most in time and capital money.

[illegible] far, all producers have been proceeding accord- [illegible] Two. Everyone has obviously done the

quickest, easiest, most effective things first. This has permitted most of us to quickly approach conformance to the emergency standard now in effect. I say "approach," because I do not believe that any PVC producer is able to stay below 50 parts per million 100 percent of the time at every location in his plant currently.

I know that we are not, in spite of our most strenuous efforts, and I believe we may be ahead of a number of other producers in measures we have taken.

Because of the volatility of VCM and the internal pressures in PVC equipment, every flange, valve, pump, compressor, agitator, reactor and other piece of process equipment is a potential source of leaks. Much of the equipment must be opened routinely for cleaning and inspection to insure safe operation, and large quantities of air pass through other items of equipment, such as centrifuges and driers. There is no one thing that can be done to limit VCM loss to the plant atmosphere; there are literally hundreds of leaks or potential leaks to deal with.

This should make it clear how hazardous are estimates of future achievable VCM levels in plant air and how likely it is that excursions in these levels will unpredictably occur from time to time. Replacement of older equipment with newer types, which are designed with minimum leakage in mind, depends upon the availability and deliverability of such replacements. Delivery of even an exhaust fan takes

There are two possible places in fabrication operations that should have some precautions in effect, however. Such precautions seem to be already adequately covered by existing OSHA requirements.

At the point where the PVC container is first opened, the contained air, although quite small in volume and in absolute VCM content, may be high in VCM concentration. In an impervious container, such as a tank car or silo, the concentration will usually be somewhat above the corresponding parts per million of free monomer in the resin. In a porous container, like a paper bag, the concentration in the contained air will be very noticeably lowered. In either case this air should be exhausted outside the work area by appropriate ventilation means.

In a similar way, gases evolving from the first heating and exposure of the molten resin should essentially be similarly vented.

With these simple precautions, the atmosphere in the fabricating work space may be expected to be at levels not exceeding two parts per million, and probably very much lower. TWA's for such plants might be expected to average one or less for the employees involved.

I would point out that these estimates presented here were given before we were aware of the data you received earlier today from these fabricating people.

16 small reactors. These reactors must be opened frequently for charging and cleaning. It is the vapors from these operations and from the VCM degassing from the slurry and dry powder that form the greatest sources of monomer exposure to workers.

The second greatest source is the fugitive emissions from leaks at gaskets, valves and valve stems, pump seals and other mechanical joints in the piping of the plants. These two sources will continue to be a problem no matter how well maintained or how carefully operated is the plant.

Monitoring of the VCM concentrations taken in our plants during the last week in January of this year disclosed that we had many areas around reactor, pumps and weigh tanks that contained concentrations in the 200 to 400 PPM range, with a few isolated points even higher, although the general work space was generally in the 50 to 200 PPM range. This survey substantiates the results of earlier tests.

At this time, APCI accelerated its monomer exposure reduction program, which had been started almost a year earlier. We mounted a major engineering and renovation program, including extensive revising of operating procedures, to reduce the chance of release of monomers inside the building, special retraining of operators, and augmentation of the total ventilation system for buildings and equipment. We instituted the use of airline respirators for reactor cleaning or entering

vessels containing monomers, and while doing maintenance work that could release monomers.

We were fortunate that we had placed on order, in the summer of 1973, much of the equipment needed for the polymer building ventilation improvements, and that this was in fact being delivered in early 1974. Other equipment was obtained from wherever available; some was diverted from its intended application in other areas for this purpose.

Immediate attention was given to the trouble spots by the assignment of all available technical and maintenance personnel. This allowed us to reduce exposure to the point that by the time the temporary standard of 50 PPM took effect on 5 April 1974, we were already in substantial compliance.

Continued work has enabled us to achieve an average eight-hour TWA in the 20 to 25 PPM range for our workers in the polymerization building, and even lower for those in some other job locations. Once again, it must be pointed out that these are average TWA figures, and that many of our results are above this average.

Moreover, we are still having difficulty in obtaining -- maintaining our workspaces below the present standard of 50 PPM ceiling all the time, since it is impossible to guarantee that a leak will not develop and that an employee will not be exposed temporarily to a concentration above the specified level, no matter what that level may be.

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interests of brevity, we are submitting these in writing as Appendix A, and ask that they be made a part of the record of this hearing. A very brief summary will be given here.

First we propose to substitute a limit of 25 TWA, 40 ceiling, in place of the no-detectable level.

Monitoring should include both the work zone and the employee.

Respirators may be of the half-face or full-face air-supplied type, and shall be worn as soon as possible after it has been detected that the ceiling has been exceeded.

Impervious suits should not be required, but clean work clothing be furnished as appropriate.

We propose that the permanent standard not apply to PVC, waste streams or finished or semi-finished product, including compound, which contains less than .05 percent by weight of uncombined vinyl chloride, or to the transportation or processing of PVC with this level of free VCM.

In conclusion, we respectfully submit that the proposed permanent standard fails to meet the basic requirements in the Occupational Safety and Health Act of 1970, either as to necessity or as to technical and economic feasibility, and that it represents a substantial departure in principle from other standards promulgated by OSHA. Many of its specific requirements are either impossible to meet or unnecessarily restrictive, and some offer greater hazards than that which

they propose to remedy.

We therefore request your serious consideration of our comments and suggested changes.

MR. FLEMING: Now, Doctor?

DOCTOR KOTIN: My name is Paul Kotin. I am a physician, graduated from University of Illinois Medical School, and my specialty is pathology; I have been a practicing pathologist and experimental pathologist during all of my career, a career which began with World War II, following which I entered the private practice of medicine in pathology for two years, went to the University of Southern California where I was, for fifteen years, leaving as the Paul Professor of Pathology.

I entered Government service in 1961 as the Scientific Director for Etiology at the National Cancer Institute; five years later served as the Founding Director of the National Institute of Environmental Health Sciences.

I was with Government until 1971, when I left to go to Temple University as Dean of the Medical School and Vice President for Health Sciences, and since June 1st of this year I have been Vice President for Health, Safety and Environment of the Johns-Manville Corporation.

My entire research career has been devoted to environmental diseases, especially environmental carcinogenesis,

and when not with the Government I worked both sides of the street; I was a consultant for a variety of Federal agencies as well as a consultant to private industry.

What I would like to do now is give you a report of the results of the screening of the present employees of Air Products and Chemicals Incorporated, who are engaged in the handling of vinyl chloride, and on the results of an examination of death certificates of those VCM employees who left the company or died while employed.

I was employed as a consultant by Mr. Richard Fleming, Group Vice President, Chemical Group of Air Products and Chemicals, in early February 1974, for the specific purpose of establishing and conducting a medical evaluation and surveillance program for employees exposed to vinyl chloride.

MR. KLEIN: Excuse me, Your Honor. If I could interrupt, our copies don't have the good Doctor's presentation.

Would you have any extra copies, Doctor?

DOCTOR KOTIN: No. Actually, I don't because it was rewritten as of last night, incorporating the most recent data from our studies of employees and data from laboratory tests. It will be submitted for the record.

JUDGE MYATT: All right, Doctor; proceed.

DOCTOR KOTIN: As a first step, two physicians were identified in the areas where Air Products has vinyl

basic array of information.

MR. KLEIN: I take it you have been monitoring considerably at present?

MR. FLEMING: Yes, that is so.

MR. KLEIN: And for approximately how long have you [illegible] monitoring your operations?

MR. FLEMING: I think Mr. Carr indicated about [illegible], and with fixed-point monitoring for a somewhat shorter period. But I think he [illegible] you that information in his testimony.

MR. KLEIN: On page ten of the testimony, you indicated that equipment must be routinely cleaned, and inspected. [illegible] what you mean by routinely cleaned?

MR. FLEMING: Well, I can give you some information [illegible]. For example, other people have commented about their frequency of reactor cleaning for you; we, of course, like the rest of the industry, must do reactor cleaning. In those reactors where we do not use solvent cleaning, we are entering those reactors to clean them somewhere in the range of four to eight batches -- each four to eight batches.

In those where we are using solvent cleaning, we go in very much less frequently, on the order of once every 35 to 40 batches, and generally speaking, the principal reason for entry is maintenance problems rather than a cleaning one.

MR. KLEIN: Is there a technical reason why solvent

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cleaning can not be used on certain types of reactors?

MR. FLEMING: Well, as in our case, as we indicated in our testimony, we have been working on the development of a solvent-cleaning technique for quite some time, and we are not satisfied with that system.

We have some significant difficulty with it, primarily in relation to recovery of solvent for re-use, separating it from the dissolved polymer, and it is in these areas that we are trying now to improve that technique.

Furthermore, the system that we have currently is not capable of treating all our reactors.

MR. KLEIN: Is there anything inherent in the reactor itself that will prevent solvent cleaning?

MR. FLEMING: Well, we are applying solvent cleaning on stainless steel reactors and on new glass-lined equipment; there is a problem in the older glass-lined equipment where the base metal behind the glass lining is not stainless steel, and there is a problem there.

The solvent cleaning cleans those holidays in the glass lining so well that you get very large accumulations of polymers sticking to the walls at that point. It is not a workable situation.

MR. KLEIN: I think you indicated that you have had some fairly recent, fairly dramatic reductions in the exposure levels. Could you indicate to us any work practices or

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knowledge concerning exposure to vinyl chloride and occurrence of angiosarcoma in experimental animals, and the occurrence of this disease in employees exposed to vinyl chloride, do you consider that a causal relationship probably exists between the exposure to vinyl chloride and induction of angiosarcoma into the livers of such employees?

DOCTOR KOTIN: I do.

DOCTOR LASSITER: Can you state at this time that none of the employees examined in your investigation have angiosarcoma of the liver?

DOCTOR KOTIN: I can, within the limits obviously of the sensitivity of our testing methods.

DOCTOR LASSITER: In other words, you are stating that none of the employees examined by you have angiosarcoma of the liver, to the best of your knowledge?

DOCTOR KOTIN: Correct.

DOCTOR LASSITER: Is it possible that some of these employees may have angiosarcoma of the liver and were not detected by your techniques?

DOCTOR KOTIN: Possibly, yes. Probably, no.

DOCTOR LASSITER: What would you have to do to make sure that none of the employees in the examination had angiosarcoma of the liver? That is, would you have to go beyond the biochemical tests for liver biopsy to assure this?

DOCTOR KOTIN: It would depend upon the state of

the cancer. If it were the early circumscribed cancer -- you must remember that the liver is an organ that has a reserve capacity of many 100 percent, and you don't begin to get significant interferences with liver function, particularly when you are dealing with a discrete entity like a cancer, in contrast to total involvement like hepatitis.

So that you can have a cancer sitting in the liver [illegible] long time before any of your tests will manifest [illegible].

So therefore I would have to answer that the size of the cancer, where it was, if it were a small cancer [illegible] to affect the bile ducts, so that it pressed [illegible] and have the patient jaundice very early in the course, we would diagnose that very, very early.

If it were in the dome, sitting under the diaphragm, where the excursions of the diaphragm may give the patient some pain with each breath, we might diagnose it early.

Alternatively, if it were seated in the right lobe of the liver right in the central portion, far removed from any of the things I have described, it could get the size of a golf ball, maybe even a baseball, before liver tests might conceivably manifest it.

This is the real problem of the diagnosis of cancer in any visceral organ: when it becomes manifest clinically.

DOCTOR LASSITER: So what you are saying here is

[illegible] although there may be the best [illegible] biochemical tests available, they would not in all certainty detect angiosarcoma of the liver.

DOCTOR KOTIN: I absolutely agree with you.

DOCTOR LASSITER: Do you recommend the screening [illegible] by all [illegible], or do you recommend that [illegible] methods you used at Air Products be used by [illegible] as a whole in screening employees for liver abnormalities?

DOCTOR KOTIN: I do.

DOCTOR LASSITER: And would this be especially true [illegible] CEA [illegible]

DOCTOR KOTIN: No; if you will notice, the alphafeto- [illegible] tests were second order tests, if you recall.

[illegible] alphafetoprotein and the CEA tests, both of [illegible] their ultimate goal the identity of the cancer [illegible] manifestation of other symptoms, like all cancer [illegible] with a reasonably high percentage of false positives and false negatives.

We know of many other diseases that give you an abnormal presence of either alphafetaprotein or carcinoembryonic antigen, so that I would be very much surprised to find the positive alphafetaprotein or a CE antigen in the absence of some other abnormal findings in the original either 12 or 18

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DOCTOR LASSITER: Then based on what we now know about vinyl chloride, is it possible to predict what a threshold of exposure would be which would not produce this disease

DOCTOR KOTIN: Yes, I think it would come -- though it is heresy, having spent 25 years working in the laboratory -- I lean with this as a personal opinion, that the laboratory has just about told us all it can in terms of the carcinogenicity of vinyl chloride.

What is necessary now is the well-designed epidemiological study of the employees exposed to vinyl chloride. Unfortunately, there are no exposure data, as we have heard again and again in the last couple of days, but it is now man, rather than the animal, that is going to have to provide us with the data for a threshold, if indeed, there is a meaningful threshold in the sense of the exposure of the total organism, man.

DOCTOR LASSITER: Well then, from the animal data, would you predict a safe threshold of exposure to vinyl chloride in terms of parts per million?

DOCTOR KOTIN: Well, I am going to say I can not predict it, but that isn't -- because I just don't think the animal data are that informative.

You are asking the data to serve as a basis for extrapolation that is not intrinsic to the data itself. By that I mean that if I say no, I do not believe -- the answer

MR. BARR: One plant, I believe, is 165 or 170 pounds. The other plant, I believe, is ten pounds higher.

MR. BELICZKY: And there is a degree of safety in [illegible] reactor operates roughly at what? 145 psi?

MR. BARR: In that area. It depends on the [illegible].

MR. BELICZKY: What is the procedure you use [illegible] have used in the case [illegible] when you have a set up [illegible] a reactor sets up and you have a fair amount of the polymer in the reactor.

[illegible] your procedure in removing it?

[illegible] you have to send a man in with [illegible] axes or saws [illegible] and cut it out.

MR. BELICZKY: Currently, are they provided with [illegible]ier [illegible] when they do this?

MR. BARR: No man in any plant goes into any vessel without [illegible] supplied respirator.

MR. BELICZKY: That is the current practice?

MR. BARR: That is the current practice.

MR. BELICZKY: When you clean a reactor to remove some of the surface coating of the polymer, do you initiate any special kind of ventilation procedure?

MR. BARR: Most assuredly!

MR. BELICZKY: Can you describe it generally?

sites, and damage, probably, to some other organs and tissues, based strictly on animal data. Doctors Peters, Munson, and Johnson presented data today which indicates that there is a possibility of cancer in other organs.

In the clinical studies that you conducted -- the biochemical testing and also the physical testing, or possibly X-rays -- did you consider damage to organs other than the liver or did you also consider other forms of cancer, other than angiosarcoma?

DR. KOTIN: We did complete physical examinations and studied all of the organs. In fact, our third order [illegible] included -- as you will recall, I mentioned this -- [illegible] upper and lower gastro-intestinal series and gall bladder visualization tests and the like, so we did consider all other possible areas of that abnormality, and the pattern that we tested with, that we applied to the employees, would have predictably identified overt disease. It is a question whether it would identify latent disease.

MR. BELICZKY: In light of the cases of angiosarcoma that have occurred in this Country and in Europe, and an indication that there may be a lag period ranging anywhere from, let's say, ten to sometimes 29 years, do you feel that your employees are still at risk?

DR. KOTIN: I think anybody is at risk who is exposed to any toxin, let alone a carcinogen.

[illegible] through what we have [illegible]

[illegible] The [illegible]um line is [illegible] the [illegible] of the cylinder. This allows both ends of the cylinder to [illegible] [illegible] to removing it. This is in contrast to [illegible] [illegible] procedures (this picture was posed).

[illegible] of the present time, even with the best designed [illegible]

[illegible]

[illegible] the technology does not [illegible] to [illegible] all sources of emissions in these large complex plants.

MR. ROWE: Thank you, Karl.

I would like now to introduce Mr. Roger Daniel, [illegible] of Industrial [illegible] for our [illegible] Division. Mr. Daniel will discuss the principles involved in [illegible] [illegible] and the significance of each [illegible]

being developed. This facility is newer than Monomer Plant No. 1 and has, as a design feature, fewer sources of emission. The overall average exposures attest to the impact of improved design on employee exposure. These two years averaged 2.2 in 1973 and 2.7 in 1974.

This facility has had a ten point area monitoring system in operation since late April [illegible] cycle time is 6 minutes per sample point and the se[illegible]ty is approximately 0.1 ppm.

(Next slide.)

Data from the various locations are shown in Table V. [illegible] [illegible] Less than [illegible] percent of the values are above 10 ppm. Examination of the raw data showed that [illegible] action had been taken within the hour and that the concentration was below 10 ppm the following hour.

(Next slide.)

Table VI contains time weighted average data for Monomer Plant No. 3. This is the newest of the three facilities and employs the latest design technology. The overall average time weighted exposure at this facility is the lowest of the three. 1.7, 1.2 and 1.2 were averages for '72 and '74 data. The problem areas are readily identified: these are the laboratory technician and the loading technician classification.

report shows the percent of the work day the employee spends at various exposure levels: 0.5 ppm; 5-10 ppm, and so forth. Note the 59[illegible] polymer operator on the day shift where 81 percent of his time was in the 0-5 ppm level and 3 percent was in the 25-30 ppm range for an eight-hour average of 5.1 ppm. The analyzer is set to alarm at 25 ppm; from the analyzer employees can determine the location of the problem. Appropriate respiratory protection is worn in the area while the problem is being corrected.

(Next slide.)

This is a summary of average exposure from February through May 1978 for the four job classifications shown on the previous daily report. These data show that levels [illegible] vary [illegible] from month to month. Note also the shift-to-shift random variation.

We have discussed the calculated TWA's from area monitoring. Now let's look at some recent personnel monitoring data. Same operator classification.

(Next slide.)

These data support the day-to-day variations observed by area monitoring.

(Next slide.)

The [illegible] operator has generally low exposure but still ~~had~~ has day-to-day variations.

Using charcoal absorption tubes short term area samples were collected to identify those operations which

bing 32
etp jr

resulted in short term release of vinyl chloride to the atmosphere.

(Next slide.)

These data collected in the fall of 1973 showed that draining the filter and brine draining both resulted in significant short term release of vinyl chloride. Engineering controls, described by Mr. Oelfke, eliminated each of these problems. An inert gas purge system is now used to clear the filter prior to change-out of the filter elements. The brine system was repiped to recycle brine to the process. This has eliminated employee exposures from each of these sources.

Short term samples using the personnel monitor are companion data to the area samples just discussed.

(Next slide)

Note the short term 1,800 ppm of the breathing zone sample collected during brine draining. The use of respirators were instigated until engineering controls were installed to eliminate this exposure.

Engineering controls have been installed in the suspension production unit that has eliminated these sources of employee exposure. In the emulsion production unit all are corrected except the reactor washout. For that operation air supplied respirators are required. Engineering studies are underway to correct this situation.

The final slide shows a comparison between eight-

y

area

monitoring

Thank you.

Mills/ms
Tape 4
f . Bing

MR. ROWE: Thank you, Roger.

We want now to return to Mr. Oelfke who will discuss the positive and negative characteristics of various types of respiratory protection and protective clothing.

Karl.

MR. OELFKE: Slide 1, Respiratory equipment is required for certain routine operations as well as for maintenance and emergency operations.

Several types of respiratory equipment have been used in the past. The most convenient and portable pieces of respiratory equipment are the cartridge and canister types. The most convenient of these is the nose-mouth cartridge respirator.

Slide 2.

It is easy to don, but does interfere with certain types of eye protection, such as chemical goggles. Its small size and light weight make it ideal to carry at all times for escape should an emergency arise.

Slide 3.

One of these canisters of approximately 100 cc was tested for breakthrough to 1 ppm at a flow of 30L per minute. It lasted 15 minutes.

Slide 4.

Next we have the full face canister type respirator. The improvement that we have here over the nose-mouth type is that the larger canister provides longer protection and eye

5-10

I believe it is, getting to 5 ppm/TWA for monomer plants.

MR. KLEIN: Could you indicate for us, please, how you arrived at the 10 ppm in 1974 and how you arrived at the 5 ppm in 1977, I think, or 1976, whatever it is?

MR. OELFKE: I don't remember what the date is. I think it is a consensus of opinion what can be done by October 5, 1974.

It is a consensus of opinion. I can only speak for our own plant.

We are really to be working towards a 5 ppm/TWA as soon -- certainly as soon as the standard -- if the SPI recommendation [illegible] we will be working, starting today, to get to a 5 ppm/TWA by 1975, October.

We would fully expect -- we have got to get to a much lower level than that for consistent 5 ppm/TWA.

MR. KLEIN: If the level were, in the future, going to be set at lower than 5 ppm, would you go about arriving at that level differently than you would if it was going to be set at 5 ppm/TWA?

MR. OELFKE: I am sorry. Would you repeat that question?

MR. KLEIN: Sure.

If the level, for example, was going to be set at one ppm, say, two or three years from now, would you go about reaching that level differently than you would if the level was

set at 5 ppm?

MR. OELFKE: I doubt it very seriously.

We have to find out where our problem areas are. And we have attempted to do so at the present time.

MR. KLEIN: I am trying to figure out how you can project what level will result from the institution of new engineering controls -- how you could say "I think we could reach 5 but we can't reach 1, 2, 3 or 4."

MR. OELFKE: I am afraid I can't answer that specific question, Mr. Klein.

MR. KLEIN: Let's talk about leaks in monomer plants [illegible] ment.

Other than what you have indicated in your testimony, are there any steps that you have taken to reduce the exposure caused by leaks?

MR. OELFKE: Preventive maintenance, I think, is the biggest step that we have tried to institute in our monomer plants.

MR. KLEIN: Could you tell us, generally, what type of preventative maintenance you found that does reduce leaks?

MR. OELFKE: Well, to start off with, you would have to find them first.

Let's assume that we have a leak. We do have a problem, as I indicated there, on our reciprocating compressors without packing purges. The packing is suitable and does reduce the

ms-2

think that there should be any unnecessary exposure of vinyl chloride.

MR. OELFKE: It has been our position in the years gone by that we reduce our exposures to all chlorinated hydrocarbons to the lowest possible limits.

MR. SAMUELS: Do you think that the rest of the industry ought to do at least as well as you do in these operations?

MR. OELFKE: I cannot testify to the rest of the industry. I am speaking of Dow's philosophy.

MR. SAMUELS: I don't mean what they can do but what they should do.

Do you think that they ought to be making the same effort?

MR. OELFKE: I think unnecessary exposure to any foreign material is a bad thing.

MR. SAMUELS: Many of the operations, if I understood the tables -- and forgive me if I couldn't read them all clearly -- but many of the operations are already below the SPI recommendations, isn't that so?

MR. OELFKE: Yes, it is.

MR. SAMUELS: Do you feel that there should be an exposure up to the SPI recommendations even though it is not necessary?

MR. OELFKE: We do not feel that the ten parts per

ms-3

million as suggested by the SPI has a license to operate at ten parts per million on a TWA.

In fact, we feel like it should be considerably lower than that on an average in order to insure that you will be below the ten parts TWA in a VCM manufacture.

MR. SAMUELS: Thank you.

Now, it seems to me, looking at the table, that at least some of the operations were even below one part per million.

Is that right?

MR. OELFKE: I believe that is correct, yes, sir.

MR. SAMUELS: So that indicates that for some operations the proposal could be met at your plant, as described, exists right now for some operations on an operation by operation basis?

MR. OELFKE: Let the data speak for itself, Mr. Samuels.

MR. SAMUELS: Do you think it is possible to further automate or otherwise redesign your process?

Not simply add supplementary controls and minor equipment changes to bring down the whole process of making vinyl chloride?

Have you been able to address -- I realize it has been a short period of time. This thing has occurred only since January. You have not been able to address yourself to

ms-5

pictures were excellent, of course, and when a -- in a loading operation, when the worker is topside, in one picture it showed the tank was open.

At that point, is it feasible for him to wear a respirator?

MR. OELFKE: No, the picture did not clearly display that he had on a respirator, but he did have on a respirator.

I put in two slides in the tank car operation. One specifically showed that he had on a respirator. The other one was a little bit [illegible]. I did not point that out, but he did have on a respirator.

MR. SAMUELS: I [illegible] see.

[illegible] can [illegible]

MR. OELFKE: No.

It was air supply, full face.

MR. SAMUELS: Full face respirator.

So it is feasible to provide a respirator for that operation and it was one of the two operations which seemed to be, if I may use the term, not in a derogatory sense, the dirtiest operation, the most exposed operation.

The laboratory technicians and the tank car operators seemed to have the highest exposure?

MR. OELFKE: That is correct, yes.

MR. SAMUELS: And for the tank car operators, at the point of highest exposure, respirators you demonstrated to be

ns-6

feasible?

MR. OELFKE: I think that it is required. I am not absolutely certain, but I think that that is required by the emergency temporary standards at the present time.

MR. SAMUELS: And you have been operating under that, and have you had any difficulties?

MR. OELFKE: We have not had any difficulty from the safety standpoint, Mr. Samuels, except our operator told me he isn't going to wear that damn thing until we figured out a way so that he wasn't exposed.

I mean, that was the kind of the way he told it.

[illegible] resistance to wearing it.

But, otherwise --

MR. OELFKE: He is wearing it, yes.

MR. SAMUELS: Okay. That's good.

Now, for the lab techs, I understood you to say that there really -- that the lab techs don't constantly analyze vinyl chloride.

MR. OELFKE: That is correct.

MR. SAMUELS: So that it would only be for short periods of time during which, if one were required, he would have to wear one.

If the hood itself weren't adequate -- I thought I saw a picture of the hood, is that right?

exposure.

The same was observed in the arsenical group, where here we had 11 observed versus 6 in the high exposure. In our lower exposures, intermediate and unmeasured area, there was essentially the same as expected.

So, again, let me go back and point out: In the exposure of intensity and duration, we do see a significant increase -- excuse me. We see an increase of malignancy over that expected, both in the arsenical and non-arsenical group.

Now let's go on to the latency report, which we discussed here. Here again in the high exposure, with 15 years plus after their initial exposure, we saw an observed death from malignancy of 8, where it was 3.2 to be expected.

Case summaries of the 13 deaths due to malignant neoplasms are shown on Table 13. Seven of the 9 individuals
952 in the high exposure group had worked for more than ten years in exposure areas; the remaining two worked for five to nine years. So these are not short-term employees in the high exposure group.

And I think it might be of interest -- again this is in detail in the record -- to give a breakdown of the cause of death and some information regarding the cause of death of our population. By the way, this was substantiated approximately by -- approximately 40 to 50 percent autopsy information; the rest from death certificates.

In the high exposure: cancer of the stomach, cancer of the lung, cancer of the lung, cancer of the rectum, cancer of squamous cell [site undetermined], leukemia, cancer of the lung, cancer of the lung, and cancer of the colon.

In our intermediate group we had two: cancer of the brain and the pancreas. The low group: one cancer of the lung; and in the indeterminate, one cancer of the lung.

Their ages of death in the years following initial exposure -- I'll just run down through the highs to give you a flavor of this: 14, 17, 17, 26, 28, 21, 27, 22, and 25 years after their initial exposure.

Full details will be in the record.

Two deaths from neoplasms were recorded on death 953 certificates as a secondary cause of death. Each death was coded in the category of diseases in the cardiovascular system. However, I think it is appropriate to cite these two deaths.

One death, the immediate cause of death was an acute myocardial infarction; however, a secondary disease of bronchiogenic carcinoma existed. He was in a low exposure group for three months' duration.

The other one was again a myocardial infarction, with a cancer of the sigmoid, or the colon, and he also was of a low exposure group.

Now let me go on and make a few, I guess I will say my opinions: One must, I think, truly consider vinyl chloride to

be a carcinogen.

However, I do feel it's appropriate to mention several other observations that we have made that would give support to the possibility of this material being an immunio-suppressant or a co-carcinogen.

Again, I fully recognize that our data is limited, and I present this posture only to stimulate further thought and possible research among the scientific arena. And this data refers back to our 13 deaths on Table 13.

One, an interesting case of acute granulocytic leukemia. During the last ten years of his employment he was not exposed to vinyl chloride, but worked in an area of benzene exposure -- controlled benzene exposure. And I think one work area, the highest excursion, only infrequently, was 50, the rest is well below the TLB.

The case of adenocarcinoma of the rectum, severe familial history: mother, two brothers and one sister died of this malignancy.

Three, of the total four lung malignancies in the high exposure group, three and probably the fourth had a history of significant cigarette smoking.

Again this raises the question as to the advisability of smoking, particularly when working with environmental carcinogens, be they vinyl chloride, asbestos, or what-have-you.

Lastly, in support of this postulate, additional

USA, and he will present and discuss data we have so far obtained relative to the metabolic pathways by which rats deal with vinyl chloride monomer.

Perry.

STATEMENT OF DR. PERRY GEHRING, DIRECTOR, TOXICOLOGY RESEARCH LABORATORY OF HEALTH AND ENVIRONMENTAL RESEARCH, DOW CHEMICAL USA

DR. GEHRING: Judge Myatt, gentlemen:

I am Perry Gehring, Director of the Toxicology Research Laboratory for the Dow Chemical Company USA.

I graduated in 1960 from the University of Minnesota with a Doctor of Veterinary Medicine degree. Subsequently I entered graduate school and received my Ph.D. in 1965, with a
956 major in pharmacology and a minor in physical chemistry.

Immediately I took a job with the Dow Chemical Company as a toxicologist. In 1968 I left Dow and took the position as associate professor of pharmacology at Michigan State University. In 1970 I returned to Dow as Assistant Director of Toxicology Research. I still retain a position as visiting professor in the Department of Pharmacology at Mighican State University.

I have authored or co-authored over 40 publications in the field of toxicology, and have presented in excess of 20 papers at scientific meetings.

I am a member of the Society of Toxicology, the

American Society of Pharmacology and Experimental Therapeutics, and the New York Academy of Sciences.

Currently I am serving on the editorial board of the official journal of the Society of Toxicology: Toxicology and Applied Pharmacology.

The basis for my testimony is the results of preliminary studies conducted in the Toxicology Research Laboratory at the Dow Chemical Company by Mr. Robert Hefner, Dr. Philip Watanabe and myself.

These studies were initially supported solely by the Dow Chemical Company. Recently, support has been by our contract with the Manufacturing Chemists Association.

The results of the studies were reported at the Vinyl Chloride Workshop sponsored by the New York Academy of Science, and the manuscript has been submitted to the Academy for publication in the Annals of the New York Academy of Science.

Copies of the manuscript, which has been submitted for publication, will be conveyed to you -- and, indeed, you already have it.

With exception of my attempts to elucidate the potential significance of what appears in that manuscript to the promulgation of work standards, the bulk of my testimony is contained in the manuscript, together with the experimental details.

I want to re-emphasize that these studies are prelimin-

ary, although conceptually important. Many of the boundaries for the ultimate interpretation of our results remain to be resolved by future studies, some of which are now underway.

Nonetheless, what we have discovered today must be considered in using a rule-of-reason approach to setting standards for vinyl chloride.

The primary objective of our studies is to elucidate the fate of vinyl chloride monomer in the body, first in rats, then in other species, and ultimately in man.

Upon learning of the carcinogenic effect of vinyl chloride, we considered the possibility that this action may occur by a direct reaction of vinyl chloride with the nucleo-

958 phelet groups of protein, DNA, RNA.

Initial attempts to react vinyl chloride with the nucleophelet sulfhydryl groups of cystine and glutathione in vitriol revealed a slight reactivity, but only under conditions considered too rigorous to be of consequence in the body.

This was consistent with our expectations, though, therefore we hypothesized that vinyl chloride may not be the ultimate or even the proximate carcinogen, and that the ultimate carcinogen is very likely produced by the degradation or metabolism of vinyl chloride in the body. This concept places a high priority on elucidation of the metabolism of vinyl chloride.

As a possible pathway for the degradation of metabolism

we hypothesized that the same pathway utilized for the metabolism of ethanol may be utilized -- that is, alcohol dehydrogenase.

If this is the case, it may be expected that the metabolites would react readily with the sulfhydryl containing amino acids, and, most importantly, that upon exposure to large amounts, the metabolism of vinyl chloride, like ethanol, by the alcohol dehydrogenase pathway, may be saturated, swamped, or overwhelmed.

If this occurred, the metabolism of vinyl chloride may be shifted to another pathway.

These thresholds for metabolic degradation of the compound must be known and considered before intelligently utilizing available toxicological and epidemiological data to establish standards for vinyl chloride, which optimize the benefit/risk relationship, however with reason.

Before I proceed with the results of our study, allow me a few more minutes to illustrate why thresholds for degradation are critical to assessing hazards.

This slide -- you cannot read the caption. Essentially what I have done here is to represent the body by a barrel, the exposure by an input source -- this being a faucet -- and the output source either by a metabolism or excretion being represented by slits, triangular, in the barrel.

If the rate of inflow is slow, as seen in the upper left, then essentially all of the material can exit from this

barrel by the slit in the lower right. As the input becomes larger, then we eventually swamp, overwhelm the first outlet means, and it begins to flow through another. And of course this can go on until we have actually swamped both outlet means.

Now, these are two and in the body there can actually be many of these.

Many substances have been shown to exhibit this type of phenomena, including aspirin, ethyleneglycol. In fact, ethyleneglycol, for example, in very low doses is metabolized completely, carbon dioxide. If you give larger doses, it is metabolized in a fashion that leads to the excretion of oxylate in the urine and these nitoses of material eventually lead to the production of bladder cancer in animals.

961 Thank you for your indulgence, and now let's proceed with the results of our preliminary studies.

The first thing we did was to determine -- I guess, first, let me show you just a brief bit about the methodology.

In this study our objective was to measure the rate at which rates metabolize vinyl chloride. This slide shows a system with which we made these measurements. You can see some rat bodies in tubes, and their heads protrude through a diaphragm into the chamber.

This is a closed system and the only exit of the vinyl chloride is due to the slow background leak, plus what the rat metabolizes. And both of those occur by first order

rates, and so you can determine the rate at which it metabolizes if you know the rate of loss from the chamber.

As the rat expired CO-2, it was picked up in an ascarite column and then makeup oxygen was injected automatically.

We monitored continuously the rate at which the vinyl chloride was removed from the chamber via a Myron-1 infrared analyzer.

Now let's go to an experiment, and here we have an experiment in which rats were exposed to between --, somewhere between 70 and 80 parts per million, as indicated by the ordinant here.

And then the disappearance, the rate of disappearance is indicated by the steepness of the slope. The upper curve or the upper line shows the rate at which it was cleared from the unoccupied chamber; and the lower, the rate at which the rats, with the rats in there, in other words, the rate at which they metabolized it.

In 7 separate experiments, at concentrations ranging from 50 to 105 parts per million, the rate constant for removal was 8 plus or minus 3 times 10 to the minus 3 minutes to the minus 1. This corresponds to a T-1 half-life of 86 minutes.

Now, when we went to the higher concentration, we found something quite different. Here the rats were exposed to near 1,000 parts per million. Again we have the rate at which the material was removed from the unoccupied chamber, and then

the rate at which it was removed from the chamber with the rats in it.

In five experiments, at initial concentrations of 220 to 1167 parts per million, the rate constant for disappearance was 2.6 plus or minus 1.3 times 10 to the minus 3. This corresponded to a T-1 half-life of 261 minutes; considerably longer.

So we do see, then, that -- I should also say at this higher concentration of 220 to 1,000 there was no consistent increase in this rate. Once you got above that level, it was the same rate constant, which indicates that above this level whatever mechanism is the secondary one is essentially the same, between these particular exposure concentrations.

96 So what we have demonstrated by this initial two studies, rather definitely is the fact that vinyl chloride is metalized by rats rather rapidly when exposed to low concentrations. However, when you exceed 220 parts per million in this case, the rate of metabolism is much slower but still first order.

Now, we had hypothesized, as I indicated, that it couldn't possibly go through the alcohol dehydrogenase pathway. And a known inhibitor of alcohol dehydrogenase is pyrazole, and so we gave this material to rats. And here we have the unoccupied chamber again, rats that were pretreated with pyrazole, and the untreated rats in the line with the steeper

slope. As you can see, pyrazole caused a rather marked inhibition at the rate at which rats metabolize this compound.

In fact, using the rate constants again, the inhibition was 71 percent, when the initial concentration was 65 parts per million. We also did this same type of experiment using the higher concentration of 1,000 parts per million, and again the pryazole caused an inhibition, which you would expect, because some would still be going through the alcohol dehydrogenase pathway; and, in addition, pyrazole does inhibit more than the alcohol dehydrogenase pathway; zambiene oxydase is another example.

To determine whether or not this was metabolism by the alcohol dehydrogenase pathway more specifically, we administered alcohol. And here are shown results of that.

The untreated rats again removed the material from the chamber very rapidly, whereas ethanol almost inhibited this 56 parts per million in initial concentration, there was 96 percent inhibition; another experiment had 97 parts per million there was 83 percent inhibition.

Going to the higher concentrations, the inhibition by alcohol was much less profound. At initial concentration of 1,025 parts per million and one experiment, the inhibition was 46 percent. In another experiment, at 1,034 parts per million the inhibition was 36 percent.

So we have, upon these experiments, that we can con-

clude that vinyl chloride is metabolized by alcohol dehydrogenase, and its metabolisms at low concentrations may be profoundly black, wherein it is not black, so that profoundly higher concentrations, which again indicates that there is a second pathway involved.

We did feel the possibility that the second pathway may be due to the microsomal oxydation, by the mixed function oxydases. There is an inhibitor of this pathway, and we gave SKF-525-A to inhibit, if possible, at least one aspect of this pathway.

Here you see exposure to concentrations between 60 and 70, again where the alcohol dehydrogenase predominates, and SKF-525-A did not produce any black.

However, it's hard to see here, but this has been duplicated in two experiments. When you give it to animals exposed to the high concentration around 1,000 parts per million SKF-525-A does cause/black.
a

Another experiment which we conducted, and I'm just going to spend a very brief time on here, is we have exposed rats for varying periods of time, seven hours per day for periods of one week, one, three, and seven weeks, to 500 parts per million; so we've varied both the exposure duration and exposure time. And then measured, subsequent to the last exposure, the sulfhydryl groups in the liver, both the protein and non-protein pre-sulfhydryl; namely glutathione and cystine.

We did this because we felt that one of the mechanisms of vinyl chloride may -- well, the metabolism of vinyl chloride by alcohol dehydrogenase produces compounds which react with these non-protein pre-sulfhydryls. And, as you can see here, exposure did cause an inhibition, or a lowering of these non-protein pre-sulfhydryl groups in the liver.

An important thing to recognize, however, is that with exposure, with the exposure duration extended, there seems to be an adaptation. This is not a dose-related response, obviously. 500, 5,000 and 15,000 do not really cause perceptible differences, and there did seem to be an adaptation.

965 I think this is important, because it has been said previously that vinyl chloride may be the ultimate carcinogen. And if vinyl chloride was the ultimate carcinogen, as Miller, at the University of Wisconsin, has stated, and many other people now, is that it is the electrophylic capacity. If the vinyl chloride was truly that electrophylic and that activated in the body, you would expect a very profound does-response relationship here. In other words, that the inhibition would definitely be related to the dose, rather than as it is.

We also examined -- excuse me. Let me tell you about initial attempts to identify metabolites before getting into this.

We did examine the urine for metabolites. We have identified S-2 hydroxyethylcystine in the rats from the previous

experiment. We also, after exposing them to 5,000 parts per million for nine weeks, we did find monochloracetic acid. We have not found it in some other subsequent experiments.

These were by -- I caution you, these were by cold methods, and so we were using thin layer chromatography, and we really have to define the boundaries of our preconceptions before we can definitely state that those are two metabolites.

We have conducted initial study using C14 vinyl chloride. Unfortunately, we don't have more results, but we found that C14 vinyl chloride polymerized very readily.

We did expose rate to 49 parts per million vinyl chloride for 65 minutes, and then, during which time they received about 5/10th of a milligram per kilogram dose, and.

966 then subsequently we removed these animals immediately from the chamber and put them into a Roth metabolism cage, which allowed the separate collection of urine, feces and expired air.

Within 15 hours, 58 percent of the C14 activity had been excreted in the urine, 3 percent in feces, 10 percent as expired carbon dioxide.

By 75 hours, the respective amounts excreted by these routes was 67, 4, and 14 percent.

Rats were killed at the end of those 75 hours, and we found 1.6 percent of the dose of C14 radioactivity given as vinyl chloride remained in the liver, 3.6 in the skin, which

was probably due to contamination and with the urine and so on, 2/10ths of a percent in kidney, and 7.6 percent in the entire remaining carcass.

I emphasize that this residual was C14 activity, not vinyl chloride. Since vinyl chloride was metabolized totally to carbon dioxide, obviously the carbons from the vinyl chloride do enter the general carbon pool, and these could be part of protein -- in other words, they are all over, and could be in many, many different types of substances in the body.

With regard to metabolites in this experiment, again we have essentially, initially identified two hydroxyethylcystine, two carboxyethylcystine, and the NS steel derivative of these; however, we do have to verify these by gaschromatographic aspect analysis.

We did not see monochloracetic acid. And again, this is important, because monochloracetic acid was not seen at
967 the low dose, but was seen at the high, which indicates that there is alternate pathways possibly occurring.

If you would turn that on again, Ted, I would like to run through the conclusion. In rats exposed to 100 parts per million or less, of vinyl chloride, the compound is metabolized readily by the alcohol dehydrogenase pathway.

Vinyl chloride metabolism by this pathway is satiable and inhibited by ethanol and pyrazole, but not by SKF-525-A.

In rats exposed to 200 parts per million or greater

of vinyl chloride, the compound is metabolized at a slower over-all rate than in rats exposed to 100 parts per million vinyl chloride or less.

However, metabolism at the higher level still follows apparent first-order rate kinetics and is partially inhibited by SKF-525-A, in addition to pyrazole and ethanol. Therefore, metabolism by the secondary pathway may be via the mixed function oxydase system of the microsome.

Exposure of rats to 50 to 1500 parts per million causes significant reduction of the non-protein pre-sulfhydryl content of the liver. The reduction is not related to the magnitude of exposure and becomes less pronounced, indeed insignificant, when continued -- with continued repeated daily exposure.

This is the biggest one. If you will bear with me. Preliminary attempts to identify metabolites have revealed carbon dioxide, S-2 hydroxyethylcystine, S-2 carboxymethylcystine, as well as NS steel derivatives.

Monochloracetic acid was found in the urine of rats exposed repeatedly to 5,000 parts per million, but not in rats exposed once to 50 parts per million.

Carbon dioxide derived by vinyl chloride is excreted in expired air. The other degradation products are excreted in the urine.

Following exposure to 50 parts per million vinyl

968

chloride, most degradation products were excreted within 15 hours. After 75 hours, about 11 percent of the total dose remained in the body, probably as metabolites. The liver had a somewhat higher level than other tissues.

As a guide to future studies we have hypothesized these pathways shown in this slide -- I'm not going to dwell much on this. The top pathway is alcohol dehydrogenase, and unfortunately the artist left out a couple of arrows.

The intermediate one is a catalase system, which has been reported in the literature and does produce peroxides, which again could produce the ultimate carcinogen.

The one that is somewhat appealing to me is the lower pathway. This is pretty far-out speculation, I suppose, but I think it is important that inorganic arsenic and thorotrast are two materials known to cause angiosarcoma.

Arsenic also causes other lesions like that of vinyl chloride. Some of the skin effects, the peripheral nervous disorders, and so on.

In 1956, Gonzales demonstrated that the biochemical lesions associated with arsenic poisoning was a reaction with 6 8-dythiooxinoid gas or alfalapoic acid.

If the epoxydase, this compound that the ethylene, chlorethylene oxide is formed, this would be a natural product that could be formed through the epoxydase pathway. It, too, would react with alfalapoic acid as arsenic, bridging the two

sulfhydryl groups and forming quite a stable compound.

And this compound, incidentally, has been reported in literature, so it is stable enough not to be too transient to

969 invoke such possibilities.

Although much of what I have presented is preliminary and speculative, I do feel our results have demonstra-ed a few points which should be considered in setting standards for vinyl chloride.

To emphasize these, let's return to the concept of metabolic degradation and elimination, as represented by the barrel, Slide 17.

Our preliminary data support the presence of at least two slits in this barrel, one of which may be saturated as the barrel fills. As this barrel -- that is, the body -- fills or the rate of input becomes larger, more of the compound is degraded by the second slit.

If the concentration is less than 100 parts per million, the bulk of the vinyl chloride appears to degrade by the lower slit. Concentrations greater than 200 parts per million, degradation by the upper pathway becomes prominent.

Although I feel degradation of vinyl chloride by the upper pathway may lead to the production of the carcinogen, it is only speculative at this time, since degradation by the lower pathway may also produce the culprit. However, this speculation is consistent with both the available toxicological

try to translate a physiological threshold to a standard for purposes of enforcement, isn't it necessary to have a margin of safety?

DR. GEHRING: Yes, it is, but you have to be very careful here. We are not, in this case, faced with a new compound for which we do not have human experience and human data.

MR. SAMUELS: No, I realize that. What are the epidemiological --

DR. GEHRING: Where exactly that threshold lies for man, obviously has not been determined.

MR. SAMUELS: Okay.

But still as a matter of enforcement, you expect the government to provide a margin of safety in translating data, physiological, epidemiological, histological, you name it, wouldn't you expect that to occur? That there be a margin.

DR. GEHRING: Again, when you talk about margin of safety, I am not disagreeing with that at all, when you have a new, unique compound.

I think the government, in this case, must consider the animal data, not isolated but together with the human data.

996 MR. SAMUELS: I would certainly agree with that, Doctor.

Now, we hear about how margins of safety are calculated. What, in food and drugs, for example, is the accepted margin of

safety? I know the Society of Toxicologists argue about this all the time, and I thought we might get this on the record.

DR. GEHRING: Well, it varies, I believe, with different materials, and I don't know whether I can even state --

MR. SAMUELS: Oh, a range, a spectrum?

DR. GEHRING: It's one/one hundredth, is one I've heard quoted.

MR. SAMUELS: All right. So that a margin of safety that might be applicable to humans might be 1/100th of the physiological level after taking into account the epidemiological data, et cetera?

DR. GEHRING: You are -- don't infer that I agree with the Food and Drug Administration.

[Laughter.]

I think that, again, has to be based upon the human experience. For example, guinea pigs given the same dose of penicilin as man is given, all die.

So, would we infer by that that we need a hundredfold margin of safety for that, when you give it to man?

So I think you have to balance all these things ala rule-of-reason again.

997

MR. SAMUELS: Whatever the rule-of-reason.

DR. GEHRING: And I'm not trying to evade your question.

MR. SAMUELS: No, I understand.

tion, I didn't. So you may want to direct that question to him. It's 500-something.

DR. HOLDER: Yes. If you want to include those who have recently, in other words, within the last five or ten years, been working there since 1960, I believe the population gets up into 700. I'm sorry. Now, that is not a solid figure. 1003 I can give you that data -- Mr. Ott, do you have that?

All right, it can be obtained. We do not have it available with us today. I'm sorry.

I would just, as a rough ballpark, if that would help you, I would say 700, 750, somewhere in there.

MS. HRICKO: So then just to clarify something. Of the people in your study, Dr. Cook, the 338 employees that you studied were only those employees who are (1) alive and (2) who were employed during '67 to '74 at Dow; is that correct?

DR. COOK: The 335.

MS. HRICKO: 335, I see.

DR. COOK: The 335 employees were the ones, by definition, who we had health surveillance data on, and we only did the procedure from 1967 to 1974; so, consequently, for them to go through the trailer, they have to be alive during that period.

MS. HRICKO: Just to clarify one other thing, then: if a worker started working with vinyl chloride at Dow in, say, 1942, they worked for 20 years with exposure to vinyl chloride

and then retired in 1962, would he or she be included in your study?

DR. COOK: He would not have gone through the health inventory trailer between 1967 and 1974, no, he would not be included.

MS. HRICKO: Because of that, then, since Dr. Holder's study is basically a mortality study, employees who have retired from the company and are alive would not be included
1004 in either study; is that correct?

DR. HOLDER: May I answer that? Have not been included, Andrea. We are, and I think we recognize this, our concern over our retired employees, and we are now actively starting a program where all retired employees, whatever their status may be, from our location, will be invited, voluntarily, to participate in a health surveillance examination, as long as they so fit, at any Dow location throughout the country.

The past study, no, these people were not included; the present, they will be. Does that answer your question?

MS. HRICKO: Yes, thank you.

I have a couple of questions, other questions for Dr. Holder.

In what process do workers at Dow get exposed to arsenicals?

DR. HOLDER: You will possibly forgive me, I'm not a chemist.

Has that association been made?

DR. HOLDER: No. No, I don't believe -- these were not our long exposures to vinyl chloride. I can give you the exposures, of the deaths, of vinyl chloride.

MS. HRICKO: That's what I would like, the exposures -- if you could submit for the record the exposure times.

DR. HOLDER: This is in the record, I believe.

MS. HRICKO: In other words, for those deaths from malignancies, the exposures to both vinyl chloride and arsenic will be assumed?

1006 DR. HOLDER: This is in the record, if you'd like to have me read this now, I would be pleased to.

MS. HRICKO: No, as long as it's in the record, that's fine. Thank you.

On the basis of your study, do you think that vinyl chloride may be a cause of multiple site cancers in man?

DR. HOLDER: Yes. Our study indicated that there was an increased malignancy rate when associated with two things: high exposure, durection and latency.

MS. HRICKO: Thank you.

How long do you normally save medical records at --

DR. HOLDER: Let me just continue this.

MS. HRICKO: Certainly.

DR. HOLDER: I cannot say that it is a carcinogen in multiple sites, because of the postulate I discussed, the

Does this answer your question?

MR. HECKMAN: I think it does. You use different starting points, is what you're saying, in effect?

DR. COOK: Different benchmarks, yes.

MR. HECKMAN: Right. That's fine. That's a perfect way to say it.

Okay. Dr. Rowe, I have a couple of questions for you. Is it true that Dow no longer produces polyvinyl chloride resin, per se?

MR. ROWE: That's correct.

MR. HECKMAN: When did you discontinue producing polyvinyl chloride resin, as such?

MR. ROWE: It was in or around about 1969.

MR. HECKMAN: Was that because it was more difficult to control emissions, or leakage, or what-have-you, of vinyl monomer from polyvinyl chloride resin in polyvinyl chloride resin plants than in what I will call polyvinylidene chloride, polyvinyl chloride plants or copolymer plants?

I don't want to use your trade name, so I'm not mentioning the name of the material.

MR. ROWE: It is my understanding that that is true. I have no firsthand knowledge of the mechanics of this, but this is what our people tell me.

MR. HECKMAN: How long would you say it has taken Dow to reach its present levels of exposure, by and large?

MR. ROWE: We'll, we started a very positive approach
1020 to reduce exposures to vinyl chloride in about 1960. That would be 14 years.

MR. HECKMAN: Thank you.

Dr. Gehring, I have just one question of you, I believe. Yes.

Dr. Gehring, the other day you questioned Dr. Keplinger of Industrial Biotest about the incidence of mortality in the mice, that Biotest has exposed to vinyl chloride.

Since there is some question about the sensitivity of mice and therefore the relevancy of using data obtained in mice to assess the hazard to man. Would you expand further on the significance of your question, and the subsequent answer you got from Dr. Keplinger?

DR. GEHRING: Yes. Subsequent to that session, I did get the most recent data from Industrial Biotest, which is the property of MCA, and the incidence in mortality after nine months of exposure are the following: control, 16 percent; 50 parts per million, 31 percent; 500 parts per million, 47 percent; and 2500 parts per million, 66 percent.

In other words, the incidence of mortality was two-fold greater than controls in those mice exposed to 50 parts per million, threefold greater in those exposed to 500 parts per million, and fourfold greater in those ex posed to 2500 parts

per million.

Now, this becomes very important when you start projecting animal data, to assess or evaluate what the risk to man might be. We know we don't have, for example, a twofold increase in mortality in man exposed to 50 parts per million, or
1021 a threefold increase in those that have been exposed to 200 and greater.

And I feel that we would certainly have picked these out.

Indeed, even in Maltoni's study, his only level, I believe, that did not cause, or rather an increase in mortality was the, either 250 or 500 parts per million.

This is very important and it's to the extent that the National Cancer Institute, in a new protocol that they issued on June 17, 1974 -- which I have a copy here, I got from them -- states, in essence, and I could read the exact statement; but in doing carcinogenic screening or evaluation, bioassay, they say no dose level shall be used that causes marked pharmacological or toxicological activity. And mortality, of course, is a rather toxic activity.

So, this rather -- in essence, the mice are truly more sensitive, I believe, to the production of hemangiosarcoma; but obviously they are much more susceptible, also, to the ____(?)____ , and really the test, I feel, is negated for projections to man.

MR. HECKMAN: Did I also understand you to say, in answer to a question that Dr. Lassiter posed, or something to this effect, that the Maltoni data could be read to mean that there is a no-effect level, taking your work into account, or possible no-effect level is what I should say, at or around 50 parts per million?

DR. GEHRING: I avoid the terminology of "no-effect level" rigorously, because --

MR. HECKMAN: Okay.

DR. GEHRING: -- as you know, our technology increases,

1022 and what was no-effect a few years ago is now -- yes, I will say no discernible effect, at least this; there is a discontinuity in his normal populations. If that were a normal population, it would be rather hard to anticipate and explain why the projected incidence of tumors wasn't true at 50 parts per million.

Although, you know, as I qualified this, that was Maltoni's data up to that point in time. This is not the case any more.

end NS/ml1

MR. HECKMAN: Well then, finally, the last question:

Do you feel that the SPI proposal in principle, not word for word, is reasonable, taking into account the state of the art in the industry in general, including the polyvinyl chloride resin production industry, as distinguished from the polyvinylidene chloride, PVC copolymer industry, in light of your evaluation of the safety data at hand, and the feasibility information that you've heard in the past few days?

Do you want me to repeat that question? Because I get -- interrupt myself with the copolymer every time.

DR. GEHRING: Yes, would you, please?

MR. HECKMAN: If I can refer to is as the coplymer, it will be easier.

Do you feel that the SPI proposal is reasonable, taking into account the state of the art in the general industry, and your evaluation of the safety data at hand at the moment?

DR. GEHRING: I'm going to say this just a bit differently. And I suspect this is the answer. There are numerous things involved in setting any level, worker, jobs, foreign trade, technology for a particular plant, and so on.

In my opinion, if I examine the toxicological data available, as well as the human data which has been shown here, there is not any discernible indication or any, at least, specific indication that 50 parts per million, for example, constitutes an unreasonable risk.

That is not to say that if the technology -- being 1024 a toxicologist, I would want people to do whatever they can to lower the risk. So I think the thing is, is that if you have the technology to reduce that level, and to get down further, that is only prudent and only makes good sense.

The part that I have in it is defining what area is reasonable risk.

MR. HECKMAN: I think that's adequate.

Thank you.

MR. KLEIN: Excuse me, Your Honor, if I may make a request: that Mr. Gehring provide for the Department of Labor the latest Biotest results that he has in his possession.

DR. GEHRING: I will ask you -- I am sure this will be the case, I am sure the MCA will give those to you, but I do not feel free to give them.

MR. KLEIN: If I may ask a question: Did Biotest indicate to you that you were not to give it to us?

DR. GEHRING: No, they did not.

MR. KLEIN: Well, is there any reason that you can think of why you shouldn't?

DR. GEHRING: No, I'm -- I just am somewhat apprehensive of, about taking the liberty of someone else's information. I'm sure they will.

JUDGE MYATT: All right, sir, if you can provide them, fine; if not, I'm sure the department can get them from MCA.

STATEMENT OF HARRY E. CONNORS, JR., VICE PRESIDENT AND GENERAL MANAGER, PLASTICS DIVISION, DIAMOND SHAMROCK CHEMICAL COMPANY

MR. CONNORS: Judge Myatt, ladies and gentlemen:

My name is Harry Connors. I am vice president of Diamond Shamrock Chemical Company, a unit of Diamond Shamrock Corporation, and I'm General Manager of the Plastics Division of the Chemical Company.

Diamond is one of the major producers of PVC resins, with production capacity equivalent to about 375 million pounds per year, which is equivalent to about 8 percent of the industry's current capacity.

Diamond purchases vinyl chloride monomer from other
1029 companies and converts that monomer into polyvinyl chloride and polyvinyl chloride copolymer resins.

We operate two PVC plants, one at Deer Park, Texas, on the Houston ship channel, and one at Delaware City, Delaware. Our Deer Park plant has been in operation for over 20 years, the Delaware plant is newer.

Total employment at the two plants is approximately 480. In addition, an estimated 75 Diamond employees at other locations in the United States depend on our PVC business for their livelihood.

Diamond's PVC production is used by approximately 280 companies in the United States, large and small, as all or part

of their raw material supply. Less than 3 percent of our PVC production is exported. Our customers for PVC include companies which manufacture plastic pipe, electrical wire and cable, packaging film and sheet, resilient floor covering, coated fabrics, and a host of specialized extruded and molded parts which find their way into almost every facet of American industry and life, but particularly automotive, household furnishings, appliances, and so forth.

Our interest in the vinyl chloride problem extends beyond our production of PVC. We are also one of the principal U. S. producers of chlorine, and a significant percentage of Diamond's chlorine is converted into VCM and ultimately into 1030 PVC.

At the other end of the spectrum, Diamond has a subsidiary in New York City, Harte and Company, which uses PVC to produce vinyl film and sheeting and vinyl molded products.

Diamond is vitally interested in the proposed OSHA standards for occupational exposure to vinyl chloride for two reasons:

First, we are concerned about the health and welfare of the workers in our plants, and we want to do all that we can to insure that our employees are not subjected to any undue hazards in connection with their employment.

Second, we want to insure that the final regulations not go beyond what is necessary to protect the health of our

Mr. Williams will report that we are presently able to achieve the 50 part-per-million emergency standard set by OSHA, and that we believe we will be able to implement further reductions in time. Specifically, we believe we will be able to comply with the exposure levels recommended earlier in these hearings by SPI, and we endorse those SPI proposals, with one exception, which I will mention shortly.

Finally, we believe the test data reported earlier by Mr. Rodney Becker of our company, that was during the course of the SPI presentation, demonstrate clearly that fabricators and compounders who use PVC resins containing less than 1/10th percent or 1,000 parts per million of vinyl chloride monomer can safely be exempt from coverage in the final regulation.

Dr. Howard Everson, who is Director of Safety and Environmental Engineering for Diamond Shamrock, will explain why we believe the SPI proposal that the exemption level be reduced in 1977 to 1/100th of one percent or 100 parts per million is unnecessary.

Diamond has produced PVC since 1953. We pride ourselves on being an efficient producer and one of the technological leaders in the industry. We employ a large number of engineers, chemists, and other technical personnel to insure that our operations are safe for our employees, and meet both customer requirements and government regulations.

In the last year alone, we have appropriated close to

$3 million for capital improvements, specifically to reduce worker exposure to VCM and VCM emissions.

As a result of these and earlier programs, we have succeeded in making dramatic reductions in the VCM levels in worker areas, and we are continuing our efforts to reduce exposure levels even further.

I would like now to introduce Dr. McBurney for his statement.

The experimental data reported in the Federal Register as justification for the proposed standard establish beyond question that vinyl chloride is a carcinogen in the animals tested.

Further, the data reveal a very definite dose-response pattern with sharply reduced carcinogenic effects as [illegible].

In my judgment, it is also proper to conclude that [illegible] as a carcinogen for man. [illegible] similarity of the angiosarcoma tumors found in vinyl chloride workers to those induced in test animals.

[illegible] determining the dose-response pattern for man. I believe there is general agreement in the scientific community that the dose-response level found to exist in test animals cannot automatically be extrapolated to determine the dose-response level for man.

Based on the available data from which conclusions may be drawn, and I refer to the mortality study by Tabershaw, the medical facts presented earlier in these hearings by Dr. [illegible], my own investigation of the medical condition of our workers and the high levels of exposure in the past, I would believe the dose-response effect for man to be higher than that in rodents.

of 50 ppm, we have obtained limited data dealing with the VCM levels of workers in our plants. These have averaged five ppm for one facility and 25 ppm for the other.

We recognize that more data will be needed, and more studies will have to be conducted before a final scientific opinion can be rendered on the carcinogenic effects of VCM in man and the exposure levels which will produce the effects.

The results of the NIOSH epidemiological studies currently underway will be of great interest and value, but these studies do not cover the entire industry. The VCM and PVC producers could make a useful contribution by conducting similar studies on present and past workers in their [illegible] plants in order to provide as complete a picture [illegible] the medical condition of workers who have been exposed to VCM.

While this additional data is being gathered and analyzed, Diamond Shamrock is exerting every effort to reduce employee exposure to VCM to the lowest possible levels.

At this time we are complying with the OSHA emergency standard of 50 ppm by the use of modified work practices, engineering changes and fresh air masks. Process redevelopment is underway, and materials are on order to further implement reductions of VCM vapors.

We endorse the gradual reductions in VCM levels as proposed by SPI. In addition, as a prudent corporation, we

are hopeful that we will be able to reach those levels in a shorter period of time, and we intend to do all that we can to attain even lower levels of exposure.

Taking into account the clear dose-response effect of VCM in the rodent population, the present good health of our workmen, the paucity of cases of angiosarcoma in the highly exposed workmen in older facilities, the facts presented in the Tabershaw mortality report and in Dr. Dernehl's testimony earlier in this hearing, and, finally, the tremendous reduction in exposure levels [illegible] has already achieved and plans to achieve in the future, I am of the opinion that our workers are at a [illegible] low risk insofar as VCM hazard is concerned.

Before concluding, I want to add a word about the medical surveillance provisions of the proposed standard.

We concur with the Department of Labor's stand that there is a need for long-term medical surveillance.

However, we disagree with the extent to which the proposed standard invades the province of the physician by spelling out in minute detail the type and timing of tests and other procedures that must be employed.

Given the wide publicity and attention the vinyl chloride problem has received, there is no reason to suggest that physicians charged with the responsibility of monitoring the health of workers exposed to vinyl chloride will not take

your statement absolutely is correct.

DR. LASSITER: You mentioned your survey, and I agree with your conclusion in charging that the industry should perhaps do some of their own epidemiology, I think that's good

1044 and I think we've seen that several in the industry are involved in their own studies, to supplement what has gone on with the MCA sponsored study and also with the NIOSH epidemiologic activities.

Of the examination of, I think it was, about 700 people, do you have anything to say -- and I won't pin you down to exact -- but in terms of years of exposure of the employees?

DR. McBURNEY: Yes, I have those broken down: 20 to 25 years, are 17; 15 to 20 years, 18; 10 to 15 years, 33; and the remainder are less than 10 years.

DR. LASSITER: Is this in the report or is this in the supplemental you had?

DR. McBURNEY: I just put it together the other day.

DR. LASSITER: Okay. Would you submit this also with the other records?

Thank you.

On page 7 of your testimony you said you were of the opinion that your workers are now at low risk, in so far as vinyl chloride hazard is concerned. We've addressed this question of risk several times during the hearings.

What do you consider to be this low risk that you

feel that your employees are being exposed to?

DR. McBURNEY: A specific number?

DR. LASSITER: Well, what do you mean by, in terms of low risk? Can you define that any further than this general statement?

DR. McBURNEY: No, and I would rather go with the general statement. I think that for years they have been exposed to much higher levels, and they are working at markedly lower levels now.

I am just drawing the conclusion from this that they are at a low risk.

DR. LASSITER: Do you have -- since you brought up the question of risk, do you have anything that you could tell the Department of Labor that would assist us in defining what risk employees should be exposed at, in terms of vinyl chloride?

DR. McBURNEY: I have addressed myself to this problem, Dr. Lassiter, and I find there's joy in my heart that I don't have to make that decision.

DR. LASSITER: Thank you.

You mention, on the same page, concerning the Department's proposed standard in terms of medical surveillance, which also is the same opinion, I think, expressed by another indutrial physician earlier, that the laboratory tests should not be specified.

Let me ask you, do you consider, in terms of what we

know about vinyl chloride and liver effects, that the tests that are specified are the ones that are necessary to determine proper liver function?

DR. McBURNEY: At this stage in time, yes; and I have no objection to specifying them. We will do them.

DR. LASSITER: Okay. I was going to ask you if you had some others you might add, but I --

DR. McBURNEY: Not at this time.

DR. LASSITER: Then, to go along with this, let me ask you if you think that all the employees that would be a possible risk would have access to a physician that's board-certified in occupational medicine, and perhaps would be as astute as the physicians you have listed here that would be charged with this responsibility? That is, do they all have access to this type of a physician?

DR. McBURNEY: I don't know whether they do or not, but I would think that it's prudent for their management to get them such physicians.

DR. LASSITER: Thank you.

MR. KLEIN: Doctor, this question may have been asked, or very close to this question may have been asked -- if you consider it the same question, you don't have to answer it. But, leaving aside the question of technical and economic feasibility, what level of exposure would you set with respect to vinyl chloride exposure to employees?

DR. McBURNEY: Mr. Klein, I think I'll duck that question, because I would rather not go on record as having to recommend anything.

I think this, and this is the whole thrust of what I said, I thought; and perhaps I didn't couch it as succinctly as I should have. 1047

But we have had plants operating since 1953 that, having talked with the management, and having talked with the workmen, and having seen what went on, that we had obviously very, very high levels; and by high, I mean thousands of parts per million.

Now, we have, as nearly as we can, we have tried to establish the health of that workman as of this period of time. And I don't find anything markedly different. Now, I haven't had enough time to do much with this work, in the hectic days.

Now, if I can look at these workmen, and I don't know -- if someone is going to ask this question -- I don't know that they aren't developing angiosarcoma now.

All I know is that at the present time they are fairly healthy, active people, and they have had little effect; and if we're to reduce this by several hundredfold, to this point of 25, 40, 50, and what's the difference between 10 and 15 and 20, it's a matter of semantics. I don't think that, as far as the body goes, I can't believe that we will be doing a great deal of harm to the workmen.